

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO 16-MD-2738 (FLW) (LHG)

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IN RE JOHNSON & JOHNSON : DAUBERT HEARING
POWDER PRODUCTS MARKETING, : JULY 31, 2019
SALES PRACTICES. : VOLUME 8
----- :

CLARKSON S. FISHER UNITED STATES COURTHOUSE
402 EAST STATE STREET, TRENTON, NJ 08608

B E F O R E: THE HONORABLE FRED A. L. WOLFSON, USDJ

A P P E A R A N C E S:

BEASLEY ALLEN, ESQUIRES
BY: P. LEIGH O'DELL, ESQUIRE (ALABAMA)
MARGARET M. THOMPSON, ESQUIRE (ALABAMA)
DAVID DEARING, ESQUIRE (ALABAMA)

-and-

ASHCRAFT & GEREL, ESQUIRES
BY: MICHELLE A. PARFITT, ESQUIRE (VIRGINIA)
On behalf of Plaintiffs Steering Committee

DRINKER, BIDDLE & REATH, ESQUIRES
BY: SUSAN M. SHARKO, ESQUIRE (NEW JERSEY)
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-and-

SKADDEN, ARPS, SLATE, MEAGHER & FLOM, ESQUIRES
BY: JOHN H. BEISNER, ESQUIRE (WASHINGTON, D.C.)

-and-

PROSKAUER ROSE, ESQUIRES
BY: BART H. WILLIAMS, ESQUIRE (CALIFORNIA)

-and-

WEIL GOTSHAL & MANGES, ESQUIRES
BY: ALLISON M. BROWN, ESQUIRE
On behalf of Defendant Johnson & Johnson

(Continued.)

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On Behalf of Defendant Personal Care Products Council

1 **M O R N I N G S E S S I O N**

2

3 (In open court.)

4 THE DEPUTY CLERK: All rise.

5 THE COURT: Thank you. Good morning.

6 Everyone may be seated.

7 MR. WILLIAMS: Your Honor, the defense calls

8 Dr. Cheryl Saenz to the stand.

9

10 **CHERYL C. SAENZ**, sworn.

11

12 DIRECT EXAMINATION

13 BY MR. WILLIAMS:

14 Q. Good morning, Dr. Saenz.

15 A. Good morning.

16 Q. Let me just orient you. There is a notebook in

17 front of you. We will be referring to that from time

18 to time. There is also a bound volume that has your

19 report in it and your CV, and things like that, in

20 case you have to refer to that more than once.

21 So let's get started.

22 Dr. Saenz, what kind of physician are you?

23 A. I'm a gynecologic oncologist.

24 Q. How long have you been treating woman with

25 gynecologic cancers?

1 A. I have been in practice for a little bit over
2 20 years, and prior to that I did a fellowship in
3 gynecologic oncology for three years.

4 Q. Where do you presently practice medicine?

5 A. I presently practice at the University of
6 California San Diego.

7 Q. How long have you been there?

8 A. Almost 21 years.

9 Q. Let's touch briefly on your educational
10 background. Where did you attend medical school?

11 A. I went to medical school at the University of
12 California, Irvine.

13 Q. And your residency?

14 A. My residency was at the University of
15 California, San Diego.

16 Q. And what was that in?

17 A. That was in reproductive medicine, also known as
18 obstetrics and gynecology.

19 Q. And, next, as I understand it, you completed a
20 fellowship. Is that right?

21 A. Yes, that's correct. I completed a fellowship
22 in gynecologic oncology at Memorial Sloan Kettering
23 Cancer Center.

24 Q. How many years was that fellowship program?

25 A. That fellowship was three years.

1 Q. What is your current title at UCSD?

2 A. I am a clinical professor in gynecologic
3 oncology in the Department of Obstetrics, Gynecology
4 and Reproductive Sciences.

5 Q. Does that job involve teaching?

6 A. Yes.

7 Q. And whom do you teach?

8 A. I teach medical students, I teach residents, and
9 I teach fellows.

10 Q. In the course of your teaching, do you discuss
11 risk factors for developing ovarian cancer with the
12 medical students and physicians that you are training?

13 A. All the time.

14 Q. What ovarian cancer risks do you teach them
15 about?

16 A. Specifically, I teach them about risk factors
17 such as age because ovarian cancer risk increases as
18 women age. I teach them about genetic risk factors
19 which can be inherited. I teach them about the
20 familial risk, meaning specifically that if they have
21 a family member that has cancer, they could be at an
22 increased risk of developing ovarian cancer as well.

23 Q. Go ahead.

24 A. Then I teach them about their own personal
25 history; and, specifically, if they had cancer, they

1 are at an increased risk.

2 And then we also talk about some other risk
3 factors, such as endometriosis, hormone replacement
4 therapy, their own reproductive history, such as
5 whether or not they've had children or not had
6 children, and the ages at which they had those
7 children, as well as factors such as when they first
8 started having their periods and when they went
9 through menopause.

10 Q. In the course of your teaching, do you ever
11 mention talc as a risk factor for developing ovarian
12 cancer?

13 A. So in my lectures I do not raise the issue of
14 talc as a risk factor for developing ovarian cancer
15 because I do not believe that it is a risk factor for
16 ovarian cancer. However, there are some learners that
17 will ask me: Well, what about talc? Because they
18 have seen news reports or read about it in another
19 venue. And I will then discuss with them the state on
20 the current literature on talc as a risk factor for
21 developing ovarian cancer.

22 Q. When you do that, do you disclose the fact that
23 you have done some work on behalf of parties in
24 litigation?

25 A. I absolutely do. And I tell them that I

1 actually have served as an expert witness for the
2 defense because oftentimes they are actually a little
3 amazed at the fund of knowledge I have on this
4 subject, but that's because I have done such a
5 thorough review of the topic.

6 Q. When did you start getting questions from
7 learners -- I think it's how you put it -- when did
8 you start getting questions about talc from your
9 students?

10 A. So I would say probably about two or three years
11 ago is when I was first asked by learners about the
12 relationship between talc and the development of
13 ovarian cancer.

14 Q. Did that coincide when you started seeing
15 reports on television?

16 A. I believe that it did.

17 Q. Could you give us an example of research that
18 you are currently conducting?

19 A. The focus of my practice actually is trying to
20 develop screening tests for the early detection of
21 ovarian cancer. I'm sure there have been other people
22 up here earlier this week that have testified that
23 screening for ovarian cancer is really quite
24 difficult, and actually at the present time, there is
25 no effective screening for ovarian cancer.

1 So one of the things that I have done is
2 partner with some of the cellular and molecular
3 medicine folks at UCSD to try and identify some
4 different biomarkers that may actually be secreted
5 into the bloodstream or identified in Pap smears.

6 Very early on in the development of ovarian
7 cancer, if we can identify those biomarkers, then we
8 could save women's lives because the survival rate
9 with Stage I ovarian cancer is much, much better than
10 with advanced stage disease.

11 Q. During the course of your career, have you
12 performed epidemiologic research?

13 A. I have.

14 Q. Can you please provide the Court with some
15 examples of that type of research that you have done.

16 A. So one of the areas that we've focused on in the
17 Division is actually endometrial cancer, and since
18 endometrial cancer, unlike ovarian cancer, has a very
19 good survival rate, mainly because it's detected early
20 since women present with vaginal bleeding.

21 We've been focusing our efforts on: What does
22 ultimately kill the women that are diagnosed with
23 endometrial cancer? Because it's not the cancer --
24 and we've published in epidemiologic studies, that if
25 a woman survives after two years after her diagnosis

1 of endometrial cancer, we have found actually it's
2 her, what we call, comorbid conditions, meaning high
3 blood pressure, obesity, cardiac disease, which is
4 most likely going to be her cause of death.

5 So we've actually taken those epidemiologic
6 studies that we've published and put together a
7 survivorship program with the women with endometrial
8 cancer to try to get them to address those other
9 comorbid diseases and perhaps reduce their mortality.

10 Q. Have you ever written an article specifically on
11 the topic of talc and ovarian cancer?

12 A. I have not.

13 Q. Why have you not published such an article?

14 A. I have not done any primary research in that
15 area. Most of my research has been focused on
16 clinical trials or things such as we discussed
17 earlier, trying to identify a screening test for
18 ovarian cancer.

19 Q. In addition to your teaching duties and
20 research, do you also treat patients?

21 A. I do.

22 Q. What percentage of your patients are ovarian
23 cancer patients?

24 A. So even though ovarian cancer is not the most
25 common gynecologic cancer, ovarian cancer patients do

1 often recur, and so they stay in your practice for
2 many, many years. This means that they end up
3 composing a much larger percent of my practice, and so
4 I would say that about 50 percent of my practice is
5 composed of women that have been diagnosed with
6 ovarian cancer.

7 Q. Over the course of your career, how many ovarian
8 cancer patients have you treated, just as an estimate?

9 A. It's in the thousands, probably close if not
10 over 2,000.

11 Q. Do all of the patients who come to see you
12 already have a diagnosis of ovarian cancer?

13 A. Well, no. Most women that are ultimately
14 diagnosed with ovarian cancer first present with a
15 pelvic mass, and you don't know whether or not it's
16 cancer. But there is also other reproductive cancers
17 that I take care of in women including uterine cancer
18 and cervical cancer, and then about, I would say,
19 20 percent of my practice is composed of women that
20 are known to be high risk for the development of
21 ovarian cancer but have not been actually diagnosed
22 with the disease.

23 Q. Is prevention of ovarian cancer part of your
24 role?

25 A. Absolutely.

1 Q. How so?

2 A. Well, women that present to my practice as high
3 risk, we place them into a screening program where we
4 obtain regular pelvic ultrasounds and CA-125s. That's
5 a tumor marker that has been associated with ovarian
6 cancer. We perform regular pelvic exams on these
7 women; and if they are not actively trying to
8 conceive, then I highly recommend that they be placed
9 on birth control pills to decrease their risk of
10 developing ovarian cancer because we know that this is
11 one of the interventions that we could make that will
12 decrease their risk by about half.

13 The other thing that we do for them is when
14 they get -- again, depending on the individual
15 mutation that they have, when there's somewhere
16 between 35 to 40 or 40 to 45 years old, we usually
17 recommend that they have surgery to physically remove
18 the tubes and ovaries because that's the only
19 intervention that's actually been shown to improve
20 survival in these women.

21 Q. Do you ask your patients whether they currently
22 use or have used talcum powder in the perineal area?

23 A. I do not.

24 Q. Why not?

25 A. Because talc is not a known risk factor for the

1 development of ovarian cancer.

2 Q. Have you ever counseled a patient not to use
3 talc?

4 A. I have not.

5 Q. Why not?

6 A. Because talc is not a known risk factor for the
7 development of ovarian cancer, nor does it cause
8 ovarian cancer.

9 Q. Now, if you believed, based on your review of
10 the scientific literature and your training and
11 experience as a gynecological oncologist that the
12 perineal use of talc did in fact cause or contribute
13 to ovarian cancer, would you tell your patients not to
14 use talcum powder?

15 A. I absolutely would, but it does not cause
16 ovarian cancer, so I do not tell them that.

17 Q. Let's turn to your opinions in this case.

18 We asked you to consider whether perineal use
19 of talcum powder products causes ovarian cancer. Is
20 that right?

21 A. That's correct.

22 Q. In your opinion, does the use of talcum powder
23 in the perineal area cause ovarian cancer?

24 A. In my opinion, perineal application of talcum
25 powder does not cause ovarian cancer.

1 Q. In your experience -- strike that.

2 In your expert opinion -- let me ask you this.
3 How did you go about your task of figuring out the
4 answer to that question?

5 A. I went about researching this question as to
6 whether or not talc is a risk factor for the
7 development of ovarian cancer, much like I would go
8 about asking any other question in the field of
9 gynecologic oncology. I did a very extensive
10 literature search. I reviewed somewhere around 30
11 case-control studies. I reviewed the four published
12 cohort studies. I reviewed seven meta-analyses and
13 one pooled analysis.

14 I went back and looked at the literature
15 surrounding what are the known established risk
16 factors for ovarian cancer, and put together a report
17 based on that research.

18 I also relied very heavily upon my experience
19 in the field practicing in the subspecialty of
20 gynecologic oncology for almost 25 years now, and
21 considered all of the patients that I have taken care
22 of that have had the diagnosis of ovarian cancer, as
23 well as the women that are in my practice and that
24 I've taken care of that are at high risk for
25 developing ovarian cancer, including all of the slides

1 that I've looked at from their surgeries, all of the
2 findings that I find when I'm operating. I relied
3 upon the breadth and depth of my experience.

4 Q. We'll get into some of those findings that
5 you've had, specifically, with regard to inflammation,
6 a little bit later. But for now, I would like to ask
7 you a question about the limitations or the impact on
8 your opinions of the asbestos.

9 Let me ask you just this one question for now.

10 Now, you understand that the defense in this
11 case vigorously disputes the methodology and
12 replicability and reliability of the analyses that
13 were done by Dr. Longo's analysts. You understand
14 that. Correct?

15 A. I understand that.

16 Q. If there were in fact trace elements of asbestos
17 in Johnson's Baby Powder, would that change any of the
18 opinions that you have given just a few moments ago
19 that talc does not cause ovarian cancer?

20 A. No, it would not.

21 Q. Why not?

22 A. The literature that is the appropriate
23 literature and the review that is the appropriate
24 review to do in this case involves the application of
25 talcum powder to the perineum, and no matter what is

1 in that talcum powder, if that was causing ovarian
2 cancer, then the literature would show an increased
3 risk of developing ovarian cancer with perineal
4 application of talc, and it does not.

5 So the constituents of the product don't
6 matter. The literature that needs to be examined and
7 the only literature in my opinion that matters is the
8 talcum powder literature.

9 Q. For purposes of your analysis of that
10 literature, did you focus on considerations of
11 strength and consistency of this association?

12 A. Absolutely. The same way that I would in my
13 practice analyzing any other question. I looked at
14 the strength of the association. I looked at the
15 consistency of the literature, both comparing the
16 literature to itself, study to study, type of study to
17 study, as well as the consistency within individual
18 study reports.

19 I also looked at the biologic plausibility.
20 Does it make sense? What the literature is reporting,
21 does it actually make sense? Is there a mechanism by
22 which this could actually be happening?

23 Q. Now, were you familiar with the proposed
24 association between the use of talc in the perineal
25 area and ovarian cancer before you began your review

1 for this lawsuit?

2 A. I was.

3 Q. How so?

4 A. Well, somewhere along my training at various
5 times I know that there have been publications on talc
6 and the risk of developing ovarian cancer. I know
7 that Dr. Cramer published the first case-control study
8 on this back in 1982. I wasn't in medical school in
9 1982. So I don't think I read that. But I do
10 remember somewhere along in my training -- be it
11 medical school, be it residency, reading some of the
12 literature and having discussions with other learners,
13 with professors about talc and the risk of developing
14 ovarian cancer.

15 Q. Now, in the course of your career, have there
16 been other hypotheses put forward in the literature
17 regarding environmental agents and an increased risk
18 of ovarian cancer?

19 A. Yes.

20 Q. Can you give me some examples?

21 A. Since ovarian cancer really is such a horrible
22 disease in terms of killing more than half of the
23 women that are diagnosed with it every year, many,
24 many people are trying to identify environmental
25 agents that may actually increase the risk of ovarian

1 cancer in the hopes of somehow impacting the incidence
2 of this disease.

3 More recently, there have actually been three
4 articles, if you will, that I actually put into my
5 report that have identified environmental agents, such
6 as television watching, which they have identified and
7 said doubles the risk of developing ovarian cancer,
8 eating processed meats, which increases the risk of
9 developing ovarian cancer by half, and taking Valium,
10 which has been reported to increase the risk of
11 developing ovarian cancer by almost 20 percent.

12 These are published manuscripts in
13 peer-reviewed literature, but nobody in the
14 gynecologic oncology community really believes that
15 these environmental exposures and reducing these
16 environmental exposures would reduce the incidence of
17 developing ovarian cancer.

18 Q. Now, the studies -- I just want to be a little
19 bit specific. The studies you cite in your report,
20 for example, for television watching, is the odds
21 ratio there 2.15 with a statistically significant
22 confidence interval?

23 A. Yes.

24 Q. And for eating processed meat, is the point
25 estimate 1.49 with a statistically significant

1 confidence interval?

2 A. Yes.

3 Q. And for the use of anxiety medication, like
4 Valium, is the risk ratio 1.17 with a statistically
5 significant confidence interval?

6 A. Yes.

7 Q. In your counsel -- do you counsel patients not
8 to watch too much TV or to not eat processed meat or
9 to not take anxiety medication in the hope of reducing
10 their risk of getting ovarian cancer?

11 A. I may counsel them to do those things, but not
12 in order to reduce their risk of ovarian cancer. For
13 other health reasons I may counsel them to do those
14 things. But reducing television watching, not eating
15 processed meat, not taking too much Valium, I don't
16 believe there is any biologically plausible mechanism
17 by which doing those things would reduce their risk of
18 ovarian cancer.

19 Q. Now, we're focused in this litigation on
20 epithelial ovarian cancer. Are there different
21 subtypes of epithelial ovarian cancer?

22 A. There are. And the different subtypes are
23 called the histologies, and the histology is how the
24 cells look under the microscope, or at least that's
25 how we used to limit our discussion.

1 Now, we actually know that the different
2 histologic subtypes actually have different origins,
3 different molecular pathways by which these different
4 histologies develop. Additionally, they responded to
5 most therapies differently. So it's not just the
6 appearance of the cell; it's also how they come about
7 to be a cancer and the ways that they respond to
8 treatments.

9 Q. Where do ovarian tumors develop? Do we know
10 this?

11 A. That's a complex question. It seems that the
12 different histologic subtypes probably originate in
13 different areas. So, for example, the serous subtype,
14 which is the most common histologic subtype, we now
15 think, based on research that has been done in the
16 last 5-to-10 years, that probably 60 to 70 percent of
17 the serous carcinomas actually come from the fallopian
18 tube. But the other 30 percent may actually still
19 originate in the ovary.

20 Q. Is it more accurate to describe ovarian cancer
21 as a single disease or as a collection of different
22 unique diseases?

23 A. They are definitely different unique diseases.
24 We know, for example, that the serous carcinomas have
25 a very different chemo response pattern than, say, the

1 mucinous carcinomas which are notoriously insensitive
2 to chemotherapy.

3 Q. Do each of those unique cancers, what you called
4 the different histologic subtypes, have different risk
5 factors associated with them?

6 A. So collectively, there are certain risk factors
7 that seem to apply to all of the different histologic
8 subtypes, but there are definitely certain risk
9 factors which seem to only impact or have influence or
10 be associated with certain subtypes.

11 Q. What about in terms of treatment; does treatment
12 vary by histologic subtypes?

13 A. Absolutely. Serous carcinomas are known to be
14 very sensitive to the platinum agents, and the
15 mucinous carcinomas don't seem to actually have any
16 sensitivity or very reduced sensitivity to the
17 platinum agents, and sometimes we actually change the
18 chemotherapy from which we typically give for ovarian
19 cancer to something that you would give for, say, a
20 gastrointestinal cancer because the mucinous ovarian
21 cancers act more like a gastrointestinal cancer.

22 Q. Let's talk about the risk factors. You
23 mentioned a bunch of them earlier today. What is a
24 risk factor?

25 A. A risk factor is something that has been

1 associated with the development of a disease. It is
2 not necessarily a causal agent. For example, if we
3 take age, age isn't causing ovarian cancer, but we
4 know that as a woman ages, her risk of developing
5 ovarian cancer increases.

6 Q. To the extent an expert were to testify that
7 risk factors for a disease and the causes of a disease
8 are the same thing, would that be correct?

9 A. No, that's not correct.

10 Q. How does something become an established risk
11 factor for ovarian cancer?

12 A. Something becomes an established risk factor by
13 epidemiologic studies being conducted to fully explore
14 the association between the risk factor and the
15 development of the disease. Typically, this would
16 start off with case reports or small series reports
17 where you might collect data on 10 or 20 patients.
18 And then a case-control study would be done in order
19 to determine whether or not there was an odds ratio
20 that was significant.

21 With that information you might then go on and
22 examine a cohort study to again try and solidify the
23 association between that risk factor and the
24 development of the disease.

25 Q. Now, you've helped us with a slide, and you've

1 already mentioned some of these, but I wanted you to
2 note for the Court that some of the established risk
3 factors in the right-hand column listed here have a
4 slightly shaded box, that is the last three,
5 endometriosis, tobacco smoking, and obesity. Why did
6 you ask us to shade that box?

7 A. I asked you to shade those boxes because those
8 risk factors are not known to be associated with the
9 entity known as epithelial ovarian cancer, but they
10 are histologic-specific.

11 So, for example, endometriosis is known to be
12 associated with the development of endometrioid and
13 clear cell carcinomas but not high grade serous
14 carcinomas.

15 Tobacco smoking is known to be associated with
16 the development of mucinous carcinomas but not the
17 other histologic subtypes.

18 Q. What, if anything, does the fact that there are
19 some risk factors that are specific to certain
20 subtypes of ovarian cancer and not others, what does
21 that tell us generally about the causes of ovarian
22 cancer?

23 A. So what that tells us and also what we know from
24 examining the molecular profiles of these different
25 histologic subtypes is that these different histologic

1 subtypes of ovarian cancer are very, very likely to
2 have different underlying causes.

3 Q. You mentioned genetic mutations earlier as a
4 risk factor. What is the increased risk associated
5 with inherited mutations?

6 A. So that depends upon what mutation you inherit.
7 The two most common inherited mutations in ovarian
8 cancer are mutations in either BRCA 1 or BRCA 2. The
9 risk of ovarian cancer with BRCA 1 is a bit higher
10 than BRCA 2. With BRCA 1 mutations, increasing the
11 risk of developing ovarian cancer is somewhere in the
12 range of 40 to 53 percent over the course of a woman's
13 lifetime.

14 Q. As compared to women who do not have that
15 mutation?

16 A. As compared to women who do not have any known
17 inherited mutations where the risk of developing
18 ovarian cancer is 1.3 percent.

19 Q. And how about BRCA 2?

20 A. So if a woman has inherited a mutation in
21 BRCA 2, her risk of developing ovarian cancer is in
22 the range of 22 to 30 percent over the course of her
23 lifetime.

24 Q. Just to put that in perspective, how would the
25 information you just gave us, which was between

1 roughly a 20 percent and a 40 percent risk over the
2 course of a woman's lifetime, how would that be stated
3 in terms of a percentage of increased risk? Are we
4 talking in the thousands of percent?

5 A. Yes, because if somebody has a 1.3 percent risk
6 of developing ovarian cancer, a 100 percent increase
7 in developing ovarian cancer, wouldn't she have a two
8 times risk of the 1.3 percent? So if you take that
9 40 percent that we talked about, that's actually
10 magnifying that 1.3 by about 4,000.

11 Q. Now, are all of the genetic mutations that
12 increase the risk for ovarian cancer found in either
13 BRCA 1 or 2? You told us that's not true?

14 A. That's not true. They are the two most common,
15 and they -- right now in terms of the state of the
16 science, they account for about 70 percent of the
17 known inherited mutations which increase the risk of
18 ovarian cancer.

19 There is another cluster of genes, if you
20 will, which accounts for another 29 percent of the
21 inherited mutations, and these genes individually
22 don't have a huge amount of responsibility for
23 inherited ovarian cancers, but together they do, and
24 that's about another, right now, 15 to 16 different
25 genes, and then the Lynch syndrome family which

1 consists of four genes, accounts for about 1 percent
2 of the inherited cancers.

3 Q. Are there any factors that decrease the
4 likelihood of getting ovarian cancer that reduce the
5 risk?

6 A. Yes. As I mentioned before, use of oral
7 contraceptives for five years or more, contiguous use,
8 can decrease the risk by about half.

9 In addition, breast feeding can reduce a
10 woman's risk of developing ovarian cancer.

11 Tubal ligation can reduce the risk of
12 developing ovarian cancer.

13 Having many children can reduce the risk of
14 ovarian cancer.

15 Q. Now, sometimes the factors that you just
16 referred to that decrease a woman's risk of developing
17 ovarian cancer are referred to as protective factors.
18 Have you seen that sometimes in the literature?

19 A. I have seen that, but I don't really use that
20 word, and I don't like that word being used in that
21 context because even a woman who has had many
22 children, breastfed each and every one of them, and
23 then had a tubal ligation, or even used birth control
24 pills, can still get ovarian cancer.

25 So those factors may reduce the risk and have

1 been shown in the epidemiologic literature to reduce
2 the risk, but it is not preventative. The only thing
3 that can prevent ovarian cancer is surgical removing
4 the tubes and ovaries.

5 Q. Do you prescribe -- strike that.

6 You mentioned earlier today you sometimes
7 prescribe birth control pills to reduce the risk of
8 ovarian cancer. Is that true?

9 A. That's correct.

10 Q. What about NSAIDs or anti-inflammatories?

11 A. I don't prescribe aspirin or nonaspirin NSAIDs
12 as a method to reduce the risk of ovarian cancer.

13 Q. Why not?

14 A. Because the literature on that is very
15 inconsistent. There have been several studies
16 published that show variances such as low dose daily
17 aspirin may reduce the risk, but then use of
18 nonaspirin NSAIDs may actually increase the risk of
19 ovarian cancer.

20 So since the epidemiologic literature on this
21 is very inconsistent, prescribing NSAIDs as a method
22 to reduce the risk of ovarian cancer is not something
23 that's accepted by the gynecologic oncology community.

24 Q. One of the issues about which there has been a
25 lot of discussion here over the past two weeks is

1 whether or not there is some sort of consensus in the
2 gynecologic oncology community that perineal talc use
3 causes ovarian cancer. And yesterday there was a
4 whole back and forth between Ms. Brown and
5 Dr. Clarke-Pearson. I'm not going to go through all
6 the different organizations, but I do want to ask you
7 this:

8 Is there in your view, based upon all of the
9 work that you have done, a general consensus within
10 the gynecologic oncology community that perineal talc
11 use causes ovarian cancer?

12 A. No. There is no consensus in the gynecologic
13 oncology community that talc causes ovarian cancer.
14 Our professional organizations do not support that
15 hypothesis.

16 Q. Now, there has been a lot of testimony regarding
17 the SGO, ACOG, the NCI, which is part of the NIH,
18 Center for Disease Control, the FDA, IARC and multiple
19 different studies that have been done.

20 My question to you is: Do any of the health
21 organizations that I just mentioned assert that the
22 data supports a causal association between talc and
23 ovarian cancer?

24 A. No, none of them do.

25 Q. Good. I want to be a little bit more specific

1 about one of those agencies, the National Cancer
2 Institute or NCI.

3 Yesterday Dr. Clarke-Pearson was critical of
4 the NCI PDQ.

5 MR. WILLIAMS: If we could bring that up,
6 that's Exhibit A 104.

7 (Pause.)

8 Q. If we could turn to page 13 of A 104.

9 Dr. Saenz, you are familiar with this
10 description of factors with inadequate evidence of an
11 association?

12 A. I am.

13 Q. I want to direct your attention to the perineal
14 talc exposure paragraph at the bottom of this page
15 which says:

16 "The weight of the evidence does not support
17 an association between perineal talc exposure and an
18 increased risk of ovarian cancer."

19 And then it goes on a little bit later to have
20 some citations there, and later on, on the next page.

21 Yesterday there was some discussion with
22 Dr. Clarke-Pearson that the studies here were old
23 studies, that it was not up to date.

24 First of all, did you listen to
25 Dr. Clarke-Pearson's testimony from the other room?

1 A. I did.

2 Q. Did you listen to all of it?

3 A. I did, except when I had to go to the bathroom.

4 Q. Do you agree with the National Cancer Institute
5 that the evidence concerning talc and ovarian cancer
6 is inadequate to establish a causal connection?

7 A. I agree with the NCI that the literature is
8 inadequate, that there is no demonstration in the
9 literature of a causal role of the perineal
10 application of talc and the development of ovarian
11 cancer.

12 Q. If we could turn to page 18.

13 There was discussion yesterday concerning this
14 portion of the PDQ, and specifically the portion that
15 talks about the purpose of the summary and the
16 reviewers and updates.

17 Have you reviewed this document?

18 A. Yes, I have.

19 Q. You see there and, in particular, the portion
20 under "Reviewers and Updates" there was some
21 discussion yesterday, Doctor, with Dr. Clarke-Pearson
22 when Ms. Brown was cross-examining him that talked
23 about this portion that refers to the methodology that
24 is used by the editorial board of the NCI.

25 Do you recall hearing that?

1 A. I do.

2 Q. It refers here in the first sentence under
3 "Reviewers and Updates," it says:

4 "This summary is reviewed regularly and
5 updated as necessary by the PDQ Screening and
6 Prevention Editorial Board, which is editorially
7 independent of the NCI."

8 And it goes on to discuss their meetings and
9 how often they discuss things.

10 Have you looked at that link there to the PDQ
11 Screening and Prevention Editorial Board?

12 A. I have not actually looked at that link. I have
13 seen this page, but I haven't clicked on that link.

14 Q. Let me show you what I'll represent to you what
15 appears when one clicks on that list, and it just
16 gives a list of the members of the editorial board.

17 MR. DEARING: Your Honor, I object to this.
18 This is a demonstration where the witness said she
19 doesn't have any knowledge about this. It's improper.
20 It's not in her report, and it wasn't in her
21 deposition.

22 MR. WILLIAMS: The reference to this document
23 is in her report, the NCI website, your Honor.

24 THE COURT: I want to see where the question
25 goes. I don't know if we're going to get more

1 specific. I think he's just going to show us what's
2 on the page.

3 MR. WILLIAMS: I'm just going to show her.

4 THE COURT: That's what I had a feeling it was
5 going to be. If there is no more information on it,
6 who the Board members are -- is that what you are
7 representing?

8 MR. WILLIAMS: That's all.

9 THE COURT: I had a feeling that's what was
10 coming. So with that basic representation.

11 BY MR. WILLIAMS:

12 Q. Dr. Saenz, I realize that you have not -- you
13 have testified, rather, that you have not personally
14 reviewed this document or gone to this link on the
15 website.

16 First, let's take a look at those two pages.
17 Does that purport to be a listing of the Screening and
18 Prevention Editorial Board members?

19 A. Yes, it does.

20 Q. Just browsing through that quickly, do you
21 recognize the medical centers and organizations with
22 which the members of that board are affiliated?

23 A. Yes, I do.

24 Q. Is it fair to say that the organizations and
25 universities with which those individuals are

1 associated are among the best medical organizations in
2 the country?

3 A. They give a fair representation of excellent
4 cancer centers across the country, yes.

5 Q. Very good. Let's switch topics.

6 THE COURT: While you are switching topics, I
7 want to ask a question of the Doctor.

8 When did you become involved in these
9 litigations?

10 THE WITNESS: I was first contacted by counsel
11 in November of 2016.

12 BY MR. WILLIAMS:

13 Q. Let's switch gears and discuss the concept of
14 biologic plausibility.

15 Dr. Saenz, what does that concept of biologic
16 plausibility mean to you?

17 A. So to me biologic plausibility means that you
18 are proposing a hypothesis, and based on that
19 hypothesis, the concept that whatever it is you are
20 proposing could actually happen is substantiated by
21 some science that has been done in the field.

22 Q. Now, does the science in your view for biologic
23 plausibility need to be proof positive?

24 A. No, it does not need to be proof positive for
25 there to be biologic plausibility, nor does it need to

1 be an exact representation of whatever is your
2 hypothesis. It can just be that there is enough
3 science to make sense and extend it.

4 So, for example, if I may, we know that
5 smoking causes lung cancer. In terms of evaluating
6 whether or not secondhand smoke can cause lung cancer,
7 you don't have to go through the process of repeating
8 everything that you did for secondhand smoke that you
9 did with smoking for you to get that it's biologically
10 plausible that secondhand smoke causes cancer.

11 Q. Do you believe there needs to be some sort of
12 scientific data that moves us from hypothesis into the
13 realm of a cohesive theory supported by the science
14 that has been done?

15 A. Absolutely. You can't just say I'm going to
16 come up with a hypothesis and not have any proof
17 whatsoever, not have any documentation of mechanism of
18 some sort that substantiates that hypothesis in order
19 to say there is biologic plausibility. That's just
20 guessing.

21 Q. For example, in this case in the last two weeks
22 there has been discussion about whether scientific
23 data indicates that talc can cause inflammation. You
24 are aware of that. Right?

25 A. Yes.

1 Q. There has been some discussion of the idea that
2 talc -- excuse me -- that inflammation is associated
3 with certain types of cancer. You are aware of that?

4 A. Yes.

5 Q. Here, based and upon your review, is there data
6 indicating that with some weight that ovarian cancer,
7 in particular, is associated with inflammation?

8 A. So, the hypothesis that has been put forth in
9 this case is that chronic inflammation leads to the
10 development of ovarian cancer, and the weight of the
11 literature that has been published does not support
12 that hypothesis.

13 That means there is not a biologically
14 plausible explanation for how chronic inflammation
15 could cause ovarian cancer.

16 Q. We'll talk a little more about inflammation a
17 little later. Let me ask you now about the topic of
18 migration.

19 MR. WILLIAMS: And if we could go to slide 5.

20 Q. Plaintiffs' experts claim that talc migrates
21 from the perineum to the ovaries. Based upon your
22 medical training and experience and your review of the
23 scientific literature, do you agree with that?

24 A. I do not agree with that.

25 Q. Can you walk us through the pathway of the

1 female reproductive track where talc particles would
2 have to traverse to get to the ovaries?

3 A. So when talcum powder is applied to the
4 genitalia, it's applied out here on the labia majora,
5 which are a rather large outer organ. It's the skin
6 surface. And the labia majora are opposed meaning
7 they are touching each other. They are naturally
8 closing off entrance into the inner anatomy.

9 Once you get past the labia majora, you
10 encounter the labia minora, which are the inner labia,
11 and these as well, are opposed, which means they are
12 closed off.

13 Beyond that you have to get over the perineal
14 body, which is a muscle to get entry into the
15 vestibule and the vagina. The vagina is naturally
16 collapsed. It's not wide open. It's why we have to
17 use speculums when we are doing pelvic exams, because
18 you can't just separate the labia and see into the
19 vagina.

20 The vagina itself is naturally about 7 to 8
21 centimeters long, sometimes a little bit longer, but
22 it's about as long as my finger, and that entire area
23 would need to be traversed to get to the cervix.

24 The cervix is another 3 to 4 centimeters, and
25 it is filled with mucus.

1 The uterus itself has an endometrial cavity,
2 which it, too, is collapsed and the anterior surface
3 opposes the posterior surface. The entry into the
4 fallopian tubes is way up at the top of the uterus,
5 and that's a small opening that then leads to the
6 fallopian tubes.

7 So there is, No. 1, no literature that has
8 ever shown any particulate matter migrating from the
9 outer labia majora to the perineum all the way to the
10 ovaries. There are studies that show placing
11 particles way up here in the posterior vagina that
12 those particles can end up being found in the
13 fallopian tubes. But placing something up here in the
14 posterior vagina is not the same as applying powder
15 out here.

16 Q. To the extent an expert were to testify that the
17 vagina is open to the outside world, would that be
18 accurate?

19 A. That is not an accurate description. It's not
20 reality. Otherwise, why would we need to place a
21 speculum into the vagina in order to see the vaginal
22 walls and see the cervix? It is not wide open. It's
23 not an open cavity. It's closed. It's collapsed, and
24 the labia are covering it.

25 Q. Is there data from the epidemiologic studies

1 that you have reviewed that informs your opinion on
2 whether it matters if talc could migrate all the way
3 to the ovary?

4 A. No, it doesn't really matter because even if
5 talc was migrating all the way from the perineum to
6 the ovary, there is still no evidence that chronic
7 inflammation is the cause of ovarian cancer. There is
8 no biologically plausible mechanism by which that
9 would be causing ovarian cancer.

10 Q. Let me ask you about some of the literature.
11 One study there has been some discussion about, the
12 Heller 1996 study, which is Exhibit A 60 in your
13 binder -- and let me grab that pointer from you.

14 You reviewed this study, Doctor, haven't you?

15 A. Yes.

16 Q. If we could direct your attention to the top of
17 the study.

18 Is this the study that there was an analysis
19 of 24 women, some of whom reported they used talc and
20 some of them did not?

21 A. Correct. There were 24 women in this study, 12
22 of whom reported that they had applied talc to their
23 perineum and the other 12 reported that they had never
24 used talc in the perineum.

25 Q. Why does it matter that there was talc that was

1 found in more of the women who reported that they had
2 not used talc in the perineal area than the women who
3 had?

4 A. Well, in this study the talc was actually found
5 in the women that reported no perineal application.
6 So what it says is that the talc got to those ovaries
7 somehow other than perineal application. So it's the
8 perineal application itself does not account for
9 finding talc in the ovaries.

10 Q. Do we know from the review of the Heller study
11 whether the talc in the ovaries got there before or
12 after the tissue was removed from the body?

13 A. We do not know that.

14 Q. How, if at all, does your opinion about whether
15 talc can cause ovarian cancer change if talc could
16 migrate to the ovary?

17 A. It doesn't change my opinion because we still
18 don't have any biologically plausible mechanism by
19 which talc being in the ovaries would then be causing
20 ovarian cancer.

21 Q. Have you reviewed studies, epidemiological
22 studies, that have analyzed associations related to
23 the introduction of talc into the vaginal area by
24 means of condoms or diaphragms?

25 A. Yes.

1 Q. Are those studies listed in your report?

2 A. Yes.

3 Q. Let's take a look at Cramer 2016, which is
4 Exhibit A 25. Let's look at Table 1 on page 4.

5 There is a table on page 4 entitled "Type,
6 Timing and Duration of Genital Talc Use."

7 Do you see that?

8 A. Yes, I do.

9 Q. What was the finding here with respect to
10 potential exposure in women with no personal use but
11 diaphragm only use?

12 A. These are women who placed talc on their
13 diaphragms, and what Cramer found in his manuscript
14 published in 2016 is that these women actually had a
15 protective effect against the development of ovarian
16 cancer in the range of about 27 percent because the
17 odds ratio for women who dusted their diaphragms with
18 talc was 0.73 with a significant confidence interval.

19 Q. Let me stop you there on the confidence
20 interval. You see this confidence interval crosses
21 the baseline of 1. Does that tell you this is not a
22 statistically significant finding?

23 A. Actually, Mr. Williams, it does not.

24 Q. Excuse me. I misspoke. This particular
25 confidence interval.

1 THE COURT: The next one does.

2 MR. WILLIAMS: Yes, I beg your pardon.

3 Q. For the diaphragm only use, this specific
4 confidence interval does not cross 1. What is the
5 significance of that?

6 A. That means it's a statistically significant
7 finding, but I don't believe this -- I don't believe
8 that dusting your diaphragm with talc would help
9 prevent ovarian cancer. I'm not going to now go tell
10 patients that, and the reason for that is the same
11 thing. There is a lack of biologically plausible
12 mechanism by which dusting your diaphragm with talc
13 would protect you against ovarian cancer.

14 Q. What, if anything, does this statistically
15 significant finding for the introduction of a
16 diaphragm with talc on it, what does it do for you in
17 terms of your analysis of the consistency of the
18 literature on the ultimate question here?

19 A. So earlier I commented on how, when I read all
20 of these studies I look for inconsistencies, even
21 within an individual study, and to me this is a
22 perfect example of that. Conceptually it makes no
23 sense that putting talc on your diaphragm, which then
24 goes in and sits at the mouth of your cervix, would
25 reduce your risk of ovarian cancer; whereas, placing

1 talc outside on the perineum, a good 7, 8 centimeters
2 away would increase your risk of ovarian cancer.
3 That's where I think the studies conflict within
4 themselves, and that's part and parcel of the reason
5 that I do not believe that the literature supports a
6 causal role of talc in the development of ovarian
7 cancer.

8 Q. Now, the next line, when I prematurely went to
9 it, that is not statistically significant relates to
10 condoms with or without diaphragm. Is that correct?

11 A. Right. And so condoms could theoretically be
12 dragging talc particles into the vagina or condoms may
13 actually be dusted with the talc, and, again, the odds
14 ratio is less than 1, showing potentially a protective
15 effect, although, as you stated, that confidence
16 interval is not significant because it crosses 1.

17 Q. Let's look at one more study really quickly on
18 this topic. It's a study about which we had much
19 discussion. It's the Penninkilampi 2018 study,
20 Exhibit A 109.

21 Did that study as well look at the question of
22 diaphragm use?

23 A. Yes.

24 Q. I'll direct your attention to page 5 of
25 Penninkilampi, Table 1, entitled "Method of Talc Use."

1 First of all, Doctor, can you tell by looking
2 at this chart how many studies were combined in the
3 Penninkilampi meta-analysis related to talc dusted
4 diaphragm use?

5 A. So from this meta-analysis, they were able to
6 identify eight of the studies that reported on
7 diaphragm use -- on talc being applied to the
8 diaphragm.

9 Q. Does Table 1 have an odds ratio for diaphragm
10 use?

11 A. Yes, it does. It has an odds ratio of 0.84,
12 which again, being less than 1 would suggest a
13 protective effect; but like we've talked about before,
14 this is not a statistically significant finding
15 because the confidence interval overlaps 1.

16 Q. Now, had the .84 odds ratio been statistically
17 significant, what kind of effect or association would
18 that have shown from the use of talc in diaphragms?

19 A. Again, that would suggest a protective effect
20 from dusting your diaphragm with talc and then
21 inserting it at the mouth of the cervix.

22 Q. Now, Table 1 also reports just below on sanitary
23 napkins with 12 studies being reviewed. Is that
24 right?

25 A. That's correct.

1 Q. How did this result, both individually and
2 collectively with what we saw in Cramer 2016, inform
3 your opinion in this case that the data and the
4 literature supports a finding that perineal use of
5 talcum powder does not cause ovarian cancer?

6 A. So, again, I find this conflict, if you will,
7 between putting talc on a diaphragm and placing it at
8 the mouth of the cervix creating a protective effect
9 just inconsistent and confusing in terms of why would
10 that be protective; but then placing it on a sanitary
11 napkin outside on your vulva increase your risk of
12 developing ovarian cancer. It doesn't make sense that
13 you are placing a talcum powder product even further
14 away from the ovary when you put it on the sanitary
15 napkin and increasing the risk, but when you place it
16 at the cervix on the diaphragm, you are decreasing the
17 risk.

18 Q. New topic. I want to ask you about your
19 clinical experience treating patients who have ovarian
20 cancer.

21 How many patients with ovarian cancer have you
22 operated on in the course of your career, roughly?

23 A. Again, it's most of the patients that I care
24 for, I've usually operated on; some patients granted
25 transfer care after they had surgery, but I would say

1 it's somewhere between 1500 to 1800.

2 Q. Have you ever seen evidence of an inflammatory
3 process during any of those procedures?

4 A. So during the procedure, the cancer itself is
5 already developed and can be inflammatory. But when
6 we look at the microscope slides, which we do with the
7 pathologist during a treatment planning conference,
8 which we have twice a month, we don't see evidence of
9 foreign body granulomas, evidence of a chronic
10 inflammatory response that would have been incited by
11 a foreign body.

12 Q. Is part of your practice to review the pathology
13 slides for the women upon whom you have operated?

14 A. I look at the pathology slides on every patient
15 upon which I perform surgery.

16 Q. In your over 20 years of practicing as a
17 gynecologic oncologist, have you ever seen evidence of
18 the inflammatory processes that you have mentioned --
19 granulomas, for example, foreign body giant cells?
20 Have you ever seen that type of evidence in your
21 ovarian cancer patients?

22 A. I've seen it if somebody had prior surgery, and
23 there was old suture material there, or if there were
24 staples that were there, the body has essentially
25 mounted an immune response to that foreign body. But

1 irrespective of that, I have not seen it.

2 Q. In addition to operating on patients who have
3 already been diagnosed with ovarian cancer, you've
4 told us that you do preventative work as well. Is
5 that right?

6 A. That's correct. I do surgery to remove the
7 tubes and ovaries of women prior to them being
8 diagnosed with ovarian cancer.

9 Q. Let me ask you about that subset of patients
10 with whom you have associated.

11 Those surgeries are conducted on your patients
12 who are at high risk for developing ovarian cancer?

13 A. Correct.

14 Q. How many surgeries of that type have you
15 performed in your career?

16 A. I never tallied them, but I do two to three a
17 month of that type of surgery. So you could do the
18 math, but I can't right now.

19 Q. You were asked about and testified in your
20 deposition about precursor lesions. What are those?

21 A. So for the women that have BRCA 1 and 2 lesions,
22 we know that those women are at an increased risk of
23 developing serous carcinomas. Recently -- and by that
24 I mean in the last five to eight years -- we have
25 become more sophisticated about being able to identify

1 changes in the cells in the fallopian tubes which
2 appear to be precursor lesions to the women that are
3 at risk for developing ovarian cancer.

4 And so in any patients that I'm doing surgery
5 prophylactically in order to reduce her risk of
6 cancer, those tissues, the ovaries and the tubes
7 undergo this special staining process in order to look
8 for those precursor lesions.

9 Q. With respect to those precursor lesions, if
10 those lesions were not removed, is the scientific
11 understanding that they would have progressed to
12 cancer?

13 A. Yes. So there is actually an acronym for those
14 lesions. They are called STICs, which stands for
15 "serous tubal intra-epithelial carcinoma," meaning
16 that the cancer is beginning to develop but it's not
17 yet invasive.

18 Within those STIC lesions we can also stain
19 for a mutation in the p53 gene.

20 THE COURT: You were using stain?

21 THE WITNESS: Stain.

22 Q. Go ahead.

23 A. It's an antibody that is actually tagged with
24 like a dye, if you will, so that the cells that have
25 the p53 mutation look a different color than the cells

1 that do not have the p53 mutation.

2 Q. Is it your practice to review the pathology for
3 these patients as well?

4 A. Yes.

5 Q. Have you seen any evidence of inflammation in
6 these patients with the STIC lesion?

7 A. No.

8 So I've looked at these specimens, if you
9 will, the tubes and ovaries of these high risk
10 patients. I've looked at the tissues that have been
11 stained to identify cells that contain p53 mutations
12 and cells that have STIC lesions or tubes that have
13 STIC lesions, and there is no associated inflammation
14 with these tissues, even though the cancer is already
15 in the process of developing.

16 Q. Let me ask you about pelvic inflammatory
17 disease, PID. There has been testimony about that.
18 Does PID cause adhesions?

19 A. PID can definitely cause adhesions.

20 Q. What are adhesions?

21 A. Adhesions are essentially scar tissue. They are
22 mainly composed of fibrin, which is a type of tissue
23 that's fibrous, like you would find in a piece of
24 meat. They can be thick. They can be filmy. They
25 are essentially leftovers from an inflammatory

1 process.

2 Q. Have you reviewed the literature on PID and
3 ovarian cancer?

4 A. I have.

5 Q. Dr. Clarke-Pearson testified yesterday that PID
6 causes ovarian cancer. Did you hear that testimony?

7 A. I did.

8 Q. Does the literature support that conclusion?

9 A. No. The literature on PID and its relationship
10 to ovarian cancer is actually fairly inconsistent.
11 PID in and of itself has not been the associated with
12 the development of ovarian cancer unless patients have
13 reported having more than one episode, and then the
14 type of ovarian cancer is not invasive epithelial
15 ovarian cancer; it's something called a borderline
16 tumor, and borderline tumors are a distinct entity
17 from the types of cancers we have been talking about
18 here.

19 Q. Does the data show that rates of ovarian cancer,
20 cancer risk increase in women with known inflammatory
21 conditions?

22 A. No. In fact, it doesn't. We know women, for
23 example, with ulcerative colitis or Crohn's disease,
24 but these women are not at an increased risk for
25 developing colon cancer, and they are inflammatory

1 conditions, but these women are not at an increased
2 risk for developing ovarian cancer.

3 Q. Is one of the cases you've reviewed, the Merritt
4 2008 study?

5 A. That's one of the case-control studies I've
6 reviewed, yes.

7 Q. Let's take a look at P 502. There has been
8 testimony about it. Can we look at page 2. I just
9 wanted to point out -- actually, page 3.

10 Who does this indicate was the sponsor of this
11 research?

12 A. The U.S. Army Medical Research and Materiel
13 Command.

14 Q. Let's look at page 3 of the document in the
15 second sentence of the second full paragraph. The
16 author states -- the first full paragraph:

17 "The aim of the current study was to further
18 examine the role of local chronic inflammation in the
19 development of epithelial ovarian cancer overall by
20 histologic subtype."

21 Was that the purpose as you understood it?

22 A. Overall and histologic subtype, yes.

23 Q. Let's look at page 5 of Exhibit P 502, Table 3.

24 What do the authors of the Merritt study
25 conclude about whether chronic inflammation causes

1 ovarian cancer?

2 A. So the authors of this study, based on actually
3 trying to examine other inflammatory conditions such
4 as PID, mumps or even endometriosis, concluded that
5 inflammation is not a reasonable hypothesis for the
6 development of ovarian cancer.

7 Q. Let's look at page 7 at the end in the
8 conclusion. It's on page 7. Just above the
9 acknowledgements in the paragraph on the right-hand
10 column, this says:

11 "However, experimental evidence that perineal
12 talc use elicits an inflammatory response in the
13 ovaries is lacking, and, overall, we conclude that
14 chronic inflammation does not play a major role in the
15 development of ovarian cancer."

16 Is that conclusion consistent with the review
17 of literature that you have done?

18 A. Yes, it is.

19 Q. Let me ask you about CA-125. We've heard
20 testimony that's a protein that is ubiquitous on
21 epithelial cells. What kinds of things elevate CA-125
22 levels?

23 A. Many things elevate a C-125 level. It's why it
24 is not a good screening test for ovarian cancer.
25 Pregnancy can elevate a CA-125 level; pelvic

1 inflammatory disease can elevate it; fibroids can
2 elevate it; pregnancy can elevate it.

3 Q. Now, Dr. Saed's experiment, one of the
4 experiments that he did, purported to find cells
5 treated with talc produce increased levels of CA-125.

6 My question is: Is an increase in CA-125
7 evidence of malignant transformation?

8 A. No.

9 Q. What, if anything, does an increased level of
10 CA-125 tell us about whether talc causes ovarian
11 cancer?

12 A. It doesn't tell us anything about whether talc
13 causes ovarian cancer because CA-125 is just a protein
14 that is being shed and can be shed for many, many
15 reasons. It doesn't elevate as part of the neoplastic
16 transformation. It's a response marker. It's not
17 initiating the cancer.

18 Q. Last topic. We're not going to do an exhaustive
19 review of all the epidemiological studies.

20 THE COURT: Excuse me. Explain what you mean
21 by "It's a response marker."

22 THE WITNESS: So in ovarian cancer, the CA-125
23 will elevate in about half of the women that have
24 ovarian cancer when it's just Stage I or Stage II.
25 But most women that it's found to be elevated in, it

1 doesn't elevate until the disease is already Stage III
2 or Stage IV.

3 So it's not even an early marker for ovarian
4 cancer. It's not there yet. So it's not elevated
5 even when the cancer is initiating in over half of the
6 women. It's only elevating after the cancer has
7 already developed.

8 THE COURT: Now, you reviewed Dr. Saed's
9 expert report?

10 THE WITNESS: I did.

11 THE COURT: Did you review his publication?

12 THE WITNESS: I had not, your Honor, by the
13 time of my deposition, but I have since read his
14 manuscript, okay.

15 THE COURT: Essentially, his report and the
16 manuscript are very similar and the findings that they
17 make.

18 THE WITNESS: I think the only major
19 discrepancy I found was that he reported in his report
20 for this matter that he treated the cells for
21 72 hours, but then in his manuscript he changed that
22 to 48 hours.

23 THE COURT: I think it's the reverse. The
24 report said 48 and the manuscript said 72. That was
25 changed at some other point. Put that aside.

1 Did you critique in your report Dr. Saed's
2 findings?

3 THE WITNESS: Not on his experiments, your
4 Honor. I really deferred that to Dr. Neel and some of
5 the other cancer biologists involved in this matter.

6 THE COURT: But as to his findings.

7 THE WITNESS: I didn't put it in my report,
8 but I'll be happy to answer any questions now.

9 THE COURT: It's not part of what you have in
10 your report. Okay.

11 I think there were some parts of it in her
12 deposition testimony that she reacted to.

13 THE WITNESS: I did get asked questions in my
14 deposition.

15 MR. WILLIAMS: I think there is some reference
16 in her report as to Dr. Saed's analysis.

17 THE COURT: There is some, but I don't know
18 how complete it is.

19 THE WITNESS: If I may, your Honor, in my
20 report I did comment on his abstract about the CA-125
21 levels, but I did not comment on the generation of
22 reactive oxygen species.

23 THE COURT: Got it. So we won't go there.

24 MR. WILLIAMS: The CA-125 reference is on page
25 31 of Dr. Saenz's report.

1 THE COURT: That I saw in there and that's as
2 far as it went.

3 Thank you.

4 BY MR. WILLIAMS:

5 Q. So the last topic I wanted to focus in on is the
6 cohort studies, and, in particular, some of the
7 testimony that we've heard over the last two weeks on
8 the Nurses' Health Study, Penninkilampi and Berge. I
9 would like to focus on that.

10 Are you familiar with the Nurses' Health
11 Study?

12 A. Yes, I am.

13 Q. How old were the women at the time of
14 enrollment?

15 MR. WILLIAMS: And if we could pull up slide
16 No. 6.

17 Q. Did you help us prepare this summary in the
18 Nurses' Health study?

19 A. I did.

20 Q. How old were the women at the time of
21 enrollment?

22 A. So at the time of enrollment in 1976 the women
23 spanned the ages of 30 to 55.

24 Q. In connection with forming your opinions in the
25 case, did you review Gertig 2000, Gates 2008 and Gates

1 2010?

2 A. Yes, I did.

3 Q. Let's focus on Gertig 2000 first.

4 Did the Nurses' Health Study obtain
5 information about perineal exposure to talc from
6 participants?

7 A. Yes, it did, although the initial study started
8 in 1976. In 1982 the study authors sent
9 questionnaires that included questions about the
10 frequency with which women were applying talc to the
11 genital area.

12 Q. How many women formed the cohort for analysis?

13 A. It was almost 79,000 women.

14 Q. How long were the women studied?

15 A. So the women in this study, this initial Gertig
16 2000 study, were followed for 14 years.

17 Q. Please take a look at Table II on page 3 of
18 Exhibit A 45. We'll have it on the slide.

19 What were the results of Gertig 2000 for ever
20 never perineal talc use for all subtypes combined?

21 A. So Gertig 2000 reported nonstatistically
22 significant relative risk for ever use of talc in
23 terms of increasing the risk of developing ovarian
24 cancer with a value of 1.09, and a nonstatistically
25 significant confidence interval of 0.86 through 1.37.

1 Q. Now, in Gertig 2000 the authors also analyzed
2 the findings for serous ovarian cancer specifically.
3 Right?

4 A. Yes, they did.

5 Q. If we look down at the bottom on Table 3 on that
6 page, page 4, I believe, of the exhibit, what was the
7 finding?

8 A. So Gertig 2000 reported for the serous histology
9 only a statistically significant risk factor of 1.40
10 with a confidence interval that was significant at
11 1.02 through 1.91.

12 Q. Now, did that statistically significant positive
13 association fall away with Gates 2010?

14 A. It fell away not only with Gates 2010 but also
15 with Gates 2008.

16 Q. Let's focus on 2010 first, and this is Exhibit
17 A 42. We prepared a slide for this one as well.

18 Is Gates 2010 another cohort looking at data
19 from the Nurses' Health Study?

20 A. I wouldn't say it's another cohort. I would say
21 it's an extension of the original cohort. Essentially
22 10 more years of time elapsed. During that time, the
23 authors collected data, again, on how many more women
24 were developing epithelial ovarian cancer. So in
25 2000, I believe there were 307 cases. By 2010, so,

1 now a full 24 years of follow-up on this cohort, there
2 were an additional almost 600 more cases. It went
3 from 307, I believe, to 876 women diagnosed with
4 epithelial ovarian cancer.

5 Q. Let me stop you there. You indicated earlier
6 that 1982 was when women were first asked about their
7 use of talcum powder. Correct?

8 A. Correct.

9 Q. Should we assume -- and did you assume in your
10 analysis that those women started using talc on the
11 date in 1982 when they filled out the form?

12 A. No, not at all, because we know from Cramer 2016
13 as well as from IARC that reported that most women
14 that used perineal talc actually usually start in
15 their twenties. And so the women in the Gertig study
16 in 1982, when they were first asked about their use of
17 talc, were well beyond that age. So I did make an
18 assumption but based off of the literature on this
19 topic, that those women were already habitual users if
20 they were users.

21 Q. Looking at Table 4 of page 8 on Exhibit 842,
22 what were the talc use categories in Gates 2010?

23 A. So in Gates 2010, they did a comparison not of
24 ever never users, but they did it of women that used
25 talc greater than one times per week versus women that

1 used it less than one time per week, which also
2 includes the never users.

3 Q. And were the results of Gates 2010 -- the Court
4 heard this before -- that there was not a
5 statistically significant association for any subgroup
6 of ovarian cancer or overall?

7 A. Correct.

8 Q. Now, let's go to the next slide.

9 Dr. McTiernan told the Court that because
10 Gertig looked at ever/never use, whereas Gates 2010
11 looked at that different metric, meaning greater than
12 once per week versus less than once per week, that you
13 just testified about, that the risk in Gates 2010 was,
14 in her words, attenuated.

15 Let me ask you this: "Attenuated" in this
16 context would mean that taking out the women who used
17 less than once per week and putting them in the
18 infrequent user category that you mentioned would
19 decrease the risk ratio for the user category. That's
20 what Dr. McTiernan was saying, right?

21 A. She's saying that by removing the women that
22 used it less than once per week from the women that
23 used it more often decreased that relative risk
24 number, she's making that assumption. Correct?

25 Q. Is Dr. McTiernan's testimony supported by the

1 studies upon which you and she relied?

2 A. No.

3 Q. Why not?

4 A. Actually, it's the opposite of what she assumed
5 and asserted. What Gates 2010 did was focus on the
6 habitual users. They did not want the risk, if there
7 was one, that would be associated with the habitual
8 users to be diluted, if you will, by the infrequent
9 users.

10 So they pulled the women out that were using
11 talc less than once per week and grouped them with the
12 never users. The intent of this was to in fact
13 magnify the risk of habitual users if in fact there
14 was a risk.

15 Q. Let's take a look at Gates 2008 to see what you
16 are saying.

17 Did Gates 2008 report on the same cohort of
18 women from the Nurses' Health Study that we saw in
19 Gertig 2000?

20 A. Yes, they did.

21 Q. Let's look at Gates 2008, Table 3. This is
22 Exhibit A 43.

23 What were the results in Gates 2008 in the
24 category of women that used talc less than once per
25 week? Was the result above 1.0 or below?

1 A. So in Gates 2008, what the authors found was
2 that the women that used talc less than 1 time per
3 week had a relative risk of 0.98, which meant their
4 risk was actually even lower than the women that were
5 never users.

6 So this is exactly what I was talking about
7 before. By grouping the never users with the less
8 than one time per week women -- you are pulling out
9 the infrequent users from your more frequent users so
10 that you could in fact magnify an effect if there was
11 actually one there.

12 Q. Using this table, can you explain to the Court
13 why the data from this study does not support
14 Dr. McTiernan's assumption about attenuation?

15 A. Dr. McTiernan is making the assumption that any
16 exposure to talc will increase your risk of ovarian
17 cancer. What this data shows is, actually, that if
18 you use talc less than one time per week, your risk is
19 no different than a never user.

20 So had these women that used less than one
21 time per week been left in the classification with the
22 users that used it one to six times per week, or more
23 often, the reported relative risk would have actually
24 been lower than what was reported in the 2010
25 publication, not higher like what was suggested by

1 Dr. McTiernan.

2 Q. And was that true for the serous subtype as
3 well?

4 A. That was true for the serous subtype as well.
5 In fact, the -- quote, unquote -- protective effect --
6 because, again, I don't believe that's really
7 protective, but the relative risk for the women that
8 used talc less than one time per week of developing
9 ovarian cancer was only 0.79. So the magnitude of
10 reduction was even greater in the women with serous
11 ovarian cancer.

12 Q. Now, is this grouping of infrequent users with
13 the never users unique to Gates 2010?

14 A. No. That attempt, if you will, with the study
15 to focus on grouping infrequent users with the never
16 users and trying to really only focus on the habitual
17 users was also done in a few of the case-control
18 studies, specifically in Schildkraut 2016, and I
19 believe in Wu 2015. Both of those study authors did
20 similar groupings of infrequent users along with the
21 never users.

22 Q. And you are familiar with the Penninkilampi
23 study?

24 A. I've am.

25 Q. Were both Wu 2015 and Schildkraut 2016 with that

1 different sort of category usage analyzed by the
2 Penninkilampi authors?

3 A. They were. Basically looking at what's called
4 -- quote, unquote -- ever users versus never users,
5 but they really weren't never users. It was more
6 never/infrequent users in both Wu 2015 and Cramer
7 2016.

8 Q. Her Honor asked the question yesterday about the
9 differences between the Penninkilampi study and the
10 Berge study. Did the Penninkilampi study even
11 consider the study that we've just gone through in
12 Gates 2010?

13 A. No. Penninkilampi did not include that cohort
14 study at all, and I don't really understand that.
15 Gertig had 14 years of follow-up. Gates 2010 had
16 24 years of follow-up. I don't know why you wouldn't
17 want to report data on a more mature study that
18 collected more cases. The authors never explained it.

19 Q. Were there other differences with respect to the
20 underlying studies used and analyzed by Penninkilampi
21 and Berge?

22 A. So with respect to the case-control studies,
23 Berge did not report -- or, I should say, Berge did
24 not include case-control studies, that the data from
25 that study had been subsumed into a later publication,

1 but Penninkilampi did.

2 So, for example, Purdie, which was published
3 in 1995, those cases were actually subsumed into Green
4 1997, and Penninkilampi included both of those studies
5 in their analysis. Berge only included the Green
6 study because that was the later publication.

7 Q. And so we see here on the slide that's on the
8 board there is a reference here to Purdie 1995. Do
9 you see that, and Green 1997?

10 A. Yes.

11 Q. And the slide on the board is summarizing a
12 chart from the Penninkilampi study?

13 A. Yes.

14 Q. Finally, Berge -- we've gone through this
15 before. Let's take a look at Table II on page 7 of
16 that study.

17 What did the Berge study find with respect to
18 whether there was a positive association between
19 perineal talc use and ovarian cancer in the cohort
20 study?

21 A. So Berge found in the cohort studies that the
22 perineal application of talc did not increase the risk
23 of developing ovarian cancer. This was utilizing all
24 three of the cohort studies and specifically not
25 utilizing the Gertig study but using the more mature

1 study in the Gates 2010 study.

2 Q. Over the past few days there has been a fair
3 amount of discussion on the subject of power as it
4 relates to case control and cohort studies.

5 What did the Berge 2018 authors conclude with
6 respect to the power of the cohort studies?

7 A. So in an attempt to try to understand I think
8 perhaps why there was a difference in the odds ratios
9 with the case-control studies versus the cohort
10 studies, the authors did a power analysis on the
11 meta-analysis of just the three cohort studies, and
12 they found that by grouping those three studies
13 together, the cohort studies were actually
14 sufficiently powered to detect a relative risk of at
15 least 1.25 if one actually existed, and this was to a
16 certainty of 0.99, which meant there is a less than
17 1 percent chance that the grouping of the cohort
18 studies together would not be capable of finding that
19 relative risk, but it means that there is a 99 percent
20 chance that these studies are actually powered to
21 detect that relative risk if it exists.

22 So the authors concluded that you can't simply
23 say that the power of the cohort studies is too low to
24 find that that's not the reason that the cohort
25 studies are not finding a statistically significant

1 increased risk.

2 Q. To summarize that finding in Berge, the cohort
3 studies had a 1.02 relative risk. Is that right?

4 A. That's correct.

5 Q. Dr. Carson testified that because the cohorts
6 were not able to find a statistically significant
7 association, that they must not have been well
8 powered.

9 My question to you is: Does that comport with
10 your understanding of the scientific method?

11 A. That's not how it works.

12 Q. Why not?

13 A. Because that would mean that any time you don't
14 have a positive finding, you are just saying the study
15 has no power. That's not how it works.

16 Q. Is that sort of like saying heads I win, tails
17 you lose?

18 A. It's kind of saying I'm going to have a positive
19 result; and if I don't get it, then I'm not getting it
20 because the study is not good. That's cherry-picking
21 your results.

22 Q. Now there has been testimony about clearance
23 from the ovary. Simple question: If something gets
24 to the ovary, for example, a talc particle or
25 bacteria, can it exit?

1 MR. DEARING: Objection. There is no evidence
2 in the report, no statements in the report about
3 clearance from the ovary.

4 MR. WILLIAMS: I believe she's qualified. She
5 didn't know people were going to make that statement
6 here, your Honor.

7 THE COURT: I know. But I am limiting
8 everyone to the opinions they have already given.

9 MR. WILLIAMS: Very well.

10 BY MR. WILLIAMS:

11 Q. Then my last question is: Could you, Doctor,
12 summarize your conclusions regarding whether the
13 literature supports a causal finding that talc causes
14 ovarian cancer with particular attention to the
15 consistency factor that you mentioned at the top?

16 A. So in my opinion the literature on whether or
17 not perineal application of talc is associated or
18 causes ovarian cancer is that the literature is
19 inconsistent. There are several case-control studies
20 that have been performed which do show an elevated
21 odds ratio in the range of 1.2 to 1.4. But there are
22 also multiple case-control studies that do not show a
23 statistically significant difference; and the analysis
24 of the cohort studies does not support, it's not
25 consistent, with the findings within the case-control

1 studies.

2 So I do not believe that the perineal
3 application of talc causes ovarian cancer.

4 MR. WILLIAMS: No further questions, your
5 Honor.

6 THE COURT: Thanks.

7 We'll take our break now.

8 THE DEPUTY CLERK: All rise.

9 (Recess.)

10 (Continued on the next page.)

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1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4 **CHERYL C. SAENZ**, resumed.

5

6 CROSS-EXAMINATION

7 BY MR. DEARING:

8 Q. Good morning.

9 Dr. Saenz, you don't have any degrees in

10 epidemiology, do you?

11 A. No, I do not.

12 Q. You are not formally trained in epidemiology,

13 are you?

14 A. I don't believe that's entirely true because, as

15 a composite part of my fellowship training in

16 gynecologic oncology, I do need to know the

17 epidemiology literature, and I do actually publish in

18 epidemiology on gynecologic cancers.

19 Q. Did you hear my question? My question was: You

20 don't have any formal training in epidemiology.

21 Correct?

22 A. And I disagree with that, sir.

23 MR. DEARING: Your Honor, permission to read

24 from her deposition?

25 THE COURT: Yes.

1 Q. Page 129, line 12.

2 MR. WILLIAMS: Your Honor, we would object.
3 It is not proper impeachment. The questions are
4 different and, therefore, the answers are different.

5 THE COURT: That is a different question.
6 Perhaps you have the wrong cite.

7 MR. DEARING: I may.

8 THE COURT: Okay.

9 BY MR. DEARING:

10 Q. Do you hold yourself out as an epidemiologist?

11 A. I do not.

12 Q. Is it true you are not formally trained in
13 epidemiology?

14 A. I do have training in epidemiology as it
15 pertains to the GYN field.

16 THE COURT: Keep your voice up. You were
17 doing great this morning.

18 Q. You are not a toxicologist, are you?

19 A. No, sir.

20 Q. And you don't have any formal training in cancer
21 biology?

22 A. I don't exactly agree with that. I actually
23 have worked as a WRHR scholar for 4 1/2 years in a
24 cancer biology laboratory, and I published in cancer
25 biology.

1 Q. You don't hold yourself out as a cancer
2 biologist, do you?

3 A. That's correct.

4 Q. And you've never published any research on the
5 issue of talc and ovarian cancer. Is that right?

6 A. That's correct.

7 Q. And you have not conducted any experiments on
8 talc and its effect on cells?

9 A. That's correct.

10 Q. And you have no opinions whether Johnson &
11 Johnson's Baby Powder or Johnson & Johnson's Shower
12 To Shower products contain asbestos. Right?

13 A. I am not giving you my opinions today, sir,
14 based on what the constituents are of the product.
15 That's correct.

16 Q. And you are not an expert on asbestos, are you?

17 A. That's correct.

18 Q. And you have no opinion whether asbestos
19 exposure can cause ovarian cancer. Right?

20 A. No, that's not entirely true. I do know that
21 IARC has published and stated that with heavy
22 occupational exposure there is an increased risk of
23 developing ovarian cancer.

24 Q. And you don't intend to offer any opinions about
25 the components of the Johnson & Johnson talc products.

1 I just mentioned their chemical compositions.

2 A. I do not.

3 Q. You don't have any opinions about whether
4 Johnson & Johnson's talc contains carcinogenic heavy
5 metals or carcinogenic fragrance chemicals. Right?

6 A. I will not be giving opinions on the
7 constituents, products or components of Johnson &
8 Johnson Baby Powder.

9 Q. And you have no opinion whether Johnson &
10 Johnson talc products contain asbestiform fibrous
11 talc. Right?

12 A. That's correct.

13 Q. And you have no opinions whether fibrous talc is
14 an established carcinogen. Right?

15 A. So I do know that IARC has published on fibrous
16 talc I believe in the asbestos monograph and grouped
17 it there, but beyond that I have no opinions.

18 Q. Are you aware that IARC has grouped fibrous talc
19 as a 1-A carcinogen, that's a known human carcinogen.
20 Right?

21 MR. WILLIAMS: Objection. Assumes facts and
22 misstates what IARC does.

23 MR. DEARING: I'm trying to clarify what she
24 just said, your Honor.

25 THE COURT: She's suggesting that's not

1 exactly the finding of IARC. If you want to direct
2 her to something, why don't you direct her to the
3 document and what you are relying on.

4 MR. DEARING: I will come back to the
5 document. I'll lay a foundation for where we are
6 going to go today.

7 THE COURT: Okay.

8 BY MR. DEARING:

9 Q. Let me ask you some questions about migration.

10 First of all, I put up two anatomy boards
11 here. First of all, where did you get the anatomy
12 slide image you talked about earlier today? Where did
13 that come from?

14 A. Counsel.

15 Q. Do you know whether it came from a textbook or a
16 Google search?

17 A. I actually helped develop that slide with
18 counsel with a medical artist.

19 Q. So that image isn't published anywhere. That's
20 an image you created?

21 A. Yes, based on what I think about female anatomy.

22 Q. Here are two other images of the female
23 reproductive tract. I just want to ask you some
24 questions about it.

25 Is it true that one of the foundational

1 building blocks of your causation opinion is that talc
2 and whatever is in talc cannot migrate from the
3 perineum to the ovaries? Is that sort of the
4 foundational pillar of your opinion?

5 A. I would not call that the foundation of my
6 opinion. I believe it's one of my opinions.

7 Q. Well, and to be more precise, what you are
8 saying is that the materials sprinkled on the external
9 genitalia can never enter the vagina. Is that your
10 opinion?

11 A. No. My opinion is that there's never been a
12 study that demonstrates application of any particulate
13 matter to the perineum can then be demonstrated to
14 show migration of that particulate matter all the way
15 to the ovary.

16 Q. Let's break that down.

17 Is it your opinion that talcum powder
18 particles sprinkled on the exterior genitalia of a
19 woman can penetrate through some circumstance into the
20 vagina?

21 A. Do I think that could happen?

22 Q. Yes.

23 A. I think that probably could happen if those
24 particles are dragged in there, say, through
25 intercourse. But I don't think there is any

1 literature that has demonstrated the main hypothesis
2 here in this case that something that is applied to
3 the external genitalia can migrate all the way to the
4 ovaries.

5 Q. I'm going to get to the ovaries in a few
6 minutes. What I'm trying to do right now is discern
7 very clearly what your opinion is with regard to
8 whether powder sprinkled on the external genitalia can
9 enter the vagina. Are you saying now that is
10 possible?

11 A. I think it's possible, but I don't know of any
12 studies that have demonstrated that.

13 Q. If a woman used Johnson's baby powder on herself
14 every day, is it your opinion that if she were to have
15 intercourse that day, that some of those particles
16 might enter the vagina?

17 A. I think that's possible.

18 Q. And you do acknowledge some particle matter,
19 when placed in the vagina, can migrate to the ovaries.
20 Right?

21 A. Yes, I've seen some studies that have
22 demonstrated that.

23 Q. And in terms of biologic plausibility, there is
24 some data there could be particulate matter that can
25 make it to the ovaries once it gets into the vagina?

1 A. There are a couple of studies that have
2 demonstrated that particulates in a slurry can then be
3 found in the fallopian tubes and ovaries under certain
4 experimental conditions.

5 Q. Would you agree with me both of these diagrams
6 demonstrate an open conduit from the vagina to the
7 ovaries?

8 A. I can't actually see that one, sir.

9 Q. I brought two diagrams because I couldn't decide
10 which one to use, and I think they both demonstrate
11 the same point. But the point is, these are
12 cross-sections of a woman's reproductive tract.

13 Right?

14 A. Yes.

15 Q. So when you look at a cross-section, you could
16 see very plainly that it's an open conduit from the
17 vagina all of the way to the fallopian tubes.

18 Correct?

19 A. So I disagree with your drawings here, sir,
20 because they do not include at all the external
21 genitalia.

22 Q. I've moved past the external genitalia to the
23 internal reproductive.

24 A. But that's part and parcel of why it is not an
25 open conduit.

1 Q. That's why I'm breaking this down into two
2 sections.

3 We just talked about powder sprinkled on the
4 outside can get inside under certain circumstances
5 such as intercourse; and now I'm talking about
6 particles, once they get inside the vagina, there is
7 an open conduit all the way to the ovaries. Right?

8 A. So, again, the vagina is not wide open like
9 that. It is collapsed. And the studies that you drew
10 my attention to earlier involve placing particles in
11 the posterior fornix at the mouth of the cervix in a
12 slurry. That's not the same thing as what your
13 drawings are showing.

14 Q. We'll talk about some of those studies in a
15 minute. I'm trying to get a foundation to figure out
16 where we are starting from.

17 Have you read the expert report of Dr. Laura
18 Plunkett in this case?

19 A. No.

20 MR. DEARING: Can you pull up 54, please.

21 Q. Dr. Plunkett identified 24 migration studies on
22 the topic of particles and their ability to migrate
23 from the vagina to the ovaries.

24 How many migration studies have you looked at?

25 A. In humans?

1 Q. In humans.

2 A. Three.

3 MR. DEARING: Can you pull up slide 5, please.

4 Q. Of course Dr. Carson and Dr. Clarke-Pearson
5 discussed six migration studies just in the last two
6 days. Are the three that you reviewed any of these
7 six?

8 A. So first I would disagree with your
9 characterization that all six of these are migration
10 studies. The talc found in tissue, 1996, which is the
11 Heller study, does not demonstrate migration. It
12 simply identifies talc in the ovaries.

13 Q. Fair enough. I didn't mean to categorize it
14 that way.

15 Let's talk about the Heller study since you
16 mentioned it. This is a study that found talc
17 particles in women who both acknowledge using talc for
18 female hygiene and women who did not. Do you agree?

19 A. Well, the women stated they applied talc to
20 their perineum. I don't know that they said they used
21 it for female hygiene.

22 But, yes, the study examined the ovaries of
23 women that applied talc to the perineum and compared
24 them to the ovaries of women that stated they did not
25 apply talc to the perineum.

1 Q. I just presumed they were doing that for
2 feminine hygiene. But my mistake.

3 Did the scientists in the Heller study
4 actually look at the ovarian tissue under a microscope
5 and detect talc particles?

6 A. I don't recall exactly how they did that
7 analysis off the top of my head, but I would be happy
8 to look at that study, sir.

9 Q. We will. I want to stay focused on migration
10 for the time being.

11 Were any of these six studies among the three
12 that you just told me that you looked at when you
13 formed your migration opinion?

14 A. So when I told you three, there were three
15 before I read my report. I've since read a couple
16 other of these studies. But prior to writing my
17 report, I did read the 1961 and the 1979 study.

18 Q. Okay.

19 MR. DEARING: Can you put up 56.

20 Q. Would you agree with me both the FDA and Health
21 Canada have determined that the ability for particles
22 applied to the perineum -- I'm sorry -- particles
23 applied to the perineum can in fact migrate to the
24 ovaries?

25 A. So I would say that the FDA and Health Canada

1 have not determined that because this is not primary
2 science. But they do make those statements, yes.

3 Q. To be specific, the FDA said:

4 "While there exists no direct proof of talc
5 and ovarian carcinogenesis, the potential for
6 particulates to migrate from the perineum and vagina
7 to the peritoneal cavity is indisputable. It is
8 therefore plausible that perineal talc and other
9 particulate that reaches the endometrial cavity, the
10 fallopian tubes, ovaries and peritoneum may elicit a
11 foreign body-type reaction and inflammatory response
12 that in some exposed women may progress to epithelial
13 cancers. However, there has been no conclusive
14 evidence to support causality."

15 So if the author of this statement has -- no
16 doubt he used the word "indisputable" as to whether
17 talcum powder applied perineally can ascend to the
18 ovaries. Correct?

19 A. That's what they say.

20 Q. Health Canada also looked at the issue and they
21 said:

22 "Biological plausibility: Particles of talc
23 are hypothesized to migrate into the pelvis and
24 ovarian tissue causing irritation and inflammation.
25 The presence of talc in the ovaries has been

1 documented," and that's the Heller study. "This
2 evidence of retrograde transport supports the biologic
3 plausibility of the association between perineal talc
4 application and ovarian exposure, however, the
5 specific mechanisms and cascade of molecular events by
6 which talc might cause ovarian cancer have not been
7 identified."

8 And that's the Taher study. Have you read the
9 Taher study?

10 A. I have.

11 Q. Do you believe the author on behalf of Health
12 Canada also says it's biologically plausible talc used
13 on the perineum can ascend to the ovaries and actually
14 cause an inflammatory response?

15 A. Well, what they actually say is that it's a
16 hypothesis, and that's in the very first line. They
17 don't have the same conclusion that you are drawing
18 that it necessarily happens. They are putting forth
19 that it's a hypothesis.

20 Q. Do you agree with them that evidence of talc in
21 the ovaries has been documented?

22 A. Yes, and I believe that Heller showed that. But
23 even Heller didn't know how that got there because the
24 women that did not report perineal application of talc
25 had shown talc in their ovaries.

1 Q. And the women who did not report using perineal
2 talc, I think a half dozen or so, isn't it true --

3 A. I'm sorry. It was actually 12.

4 Q. Okay. Isn't it true of those 12 women who did
5 not report using talc perineally, that they either
6 gave a positive history of being diapered with talcum
7 powder or they didn't know whether they were diapered
8 with talcum powder?

9 A. So what Heller reported was that since they
10 denied using perineal application of talc, she
11 hypothesized that perhaps they had been diapered when
12 they were children with talc.

13 Q. Well, six of the women actually stated
14 affirmatively that they knew they were diapered with
15 talc. Do you remember that?

16 A. No, not specifically.

17 Q. Can you pull up PSC 80. This was the IARC 2012
18 monograph excerpt.

19 Are you familiar with this monograph?

20 A. No.

21 Q. Would you turn to page 232. This is in your
22 binder, if you prefer to look at it there. I'm going
23 to show you a short excerpt. Hopefully you could see
24 it from there.

25 Down at the bottom left-hand corner, where it

1 says "human exposure," that this is IARC explaining
2 human exposure to cosmetic talc, and I would like to
3 read this to you. They are describing exposure of the
4 general population, and what they are saying is:

5 "Consumer products, cosmetics and
6 pharmaceuticals are the primary sources of exposure to
7 talc for the general population. Inhalation and
8 dermal contact through perineal application of talcum
9 powders are the primary routes of exposure."

10 Do you agree with that statement of IARC that
11 the primary route of exposure for women would be
12 either inhalation or perineal application of talcum
13 powders?

14 A. So I've not studied, nor do I have an opinion on
15 the inhalation of talc.

16 Q. Okay.

17 A. I only focused my review on the perineal
18 application of talc.

19 Q. And I knew that. I only mentioned inhalation
20 because they do. I'm more focused on the perineal
21 application.

22 Do you disagree with IARC that the perineal
23 application would be the primary exposure source for a
24 woman for talcum powder?

25 A. I have no reason to disagree with this

1 statement. But I've not studied any other type of
2 application.

3 MR. DEARING: Would you pull up PSC 5, please.
4 That's the Langseth study.

5 Q. Are you familiar with the Langseth study?

6 A. Which one?

7 MR. DEARING: Can you blow up the title and
8 the date, please.

9 Q. Are you familiar with this study?

10 A. May I see the abstract to see if this is one
11 that I've reviewed?

12 Q. It's in your binder. It's PSC General Causation
13 Exhibit 5. In my second binder it's the first study.

14 Can you read the abstract?

15 A. Yes.

16 I don't know that I've actually seen this
17 particular paper. If it's in my report, then I have,
18 or in my additional lists, but I don't know that I've
19 actually seen this particular paper.

20 Q. As you sit here right now, you don't remember
21 this paper, is that what you are saying?

22 A. As I sit here right now, I don't remember this
23 paper.

24 Q. Look at the second paragraph of this first page.
25 What it says is:

1 "From pathological studies it is known that
2 particles and fibers that enter the body can migrate
3 to distant organs. For instance, asbestos fibers have
4 been found in ovaries from women exposed to asbestos.
5 Analogously following perineal application, talc
6 particles can migrate from the vagina to the
7 peritoneal cavity and the ovaries."

8 Did I read that correctly?

9 A. Yes.

10 Q. It goes on to say:

11 "A majority of woman experience retrograde
12 menstruation. This suggests a mechanism by which talc
13 particles can travel through the female reproductive
14 tract to the ovaries. Furthermore, epidemiological
15 studies have shown decreased risks of ovarian cancer
16 after tubal ligation and for hysterectomy suggesting
17 that removing a pathway by which carcinogenic
18 substances can reach the ovaries reduces the risk."

19 Do you agree with the statements in that
20 paragraph?

21 MR. WILLIAMS: May I interpose an objection?
22 My book from plaintiffs does not have PSC 5. It's
23 missing. I want to make sure I know which Langseth
24 we're talking about.

25 MR. DEARING: I'll give you mine.

1 BY MR. DEARING

2 Q. Do you agree with the paragraph I just read?

3 A. So what the authors are putting forth here in
4 their introduction is, again, more of the hypothesis
5 that talc applied to the perineum can make it to the
6 vagina and the ovaries. That's a hypothesis. There
7 is no data, if you will, that that actually occurs.

8 I do agree that retrograde menstruation
9 exists, but this is the authors putting forth the same
10 hypothesis that we discussed earlier.

11 Q. Well, would you agree with me the first sentence
12 is not a hypothesis; it's a statement of fact from
13 pathological studies: "It is known that particles and
14 fibers that enter the body can migrate to distal
15 organs."

16 You agree with that statement, don't you?

17 A. I agree with that statement, but I don't know
18 where those things are getting in because they are not
19 specific about talking about the entry.

20 Q. Are you aware that the talc particles that are
21 found in the bottles of Johnson & Johnson Baby Powder
22 and Shower To Shower average to be about 5-to-10
23 microns in size? Are you aware of that?

24 A. No. I have no opinion on the size of talc
25 particles.

1 Q. Just to show you I'm not making this up --

2 MR. DEARING: -- can you pull up plaintiffs'

3 PSC Exhibit 76. This is the Cramer 2007 study.

4 Q. And I think you may have referenced it in your
5 direct examination.

6 A. I don't believe so, sir.

7 THE COURT: She did, 2016.

8 MR. DEARING: Okay. I'm sorry.

9 Q. If you would, please, take a look at the second
10 page of this study. It's also in your binder. All of
11 these will be in your binder.

12 MR. DEARING: The second page of the study,
13 and if you could highlight on the left-hand column
14 about two thirds of the way down in that paragraph
15 where the sentence starts "scanning electron
16 microscopy."

17 Q. Now, these are scientists from Harvard, right?
18 Dan Cramer, Dr. William Welch, Dr. John Godleski. Are
19 you familiar with those names? They've published
20 several times in this area.

21 A. I'm familiar with Dr. Cramer's name, and I'm
22 familiar with Dr. Godleski's name. I'm not familiar
23 with Dr. Welch.

24 MR. WILLIAMS: Your Honor, may we have the
25 exhibit number again?

1 THE COURT: It's 76.

2 MR. WILLIAMS: Thank you.

3 BY MR. DEARING:

4 Q. Dr. Godleski's name is familiar to you because
5 the two of you have actually testified in two of the
6 same cases. Right?

7 A. I've never seen Dr. Godleski testify, but I have
8 no reason to not believe you, sir.

9 Q. He's a pulmonary pathologist, but he's also an
10 analytical microscopist. He specializes in scanning
11 electron microscopy. And, so, in this study they were
12 looking at the presence of talc in the pelvic lymph
13 nodes of a woman, and what they observed was that the
14 talc particles they saw they averaged in range from
15 5-to-10 microns in size.

16 So to read from the study, it says:

17 "Scanning electron microscopy revealed
18 plate-like particulates in the 5-to-10-micron range
19 within the lymph node, in which energy dispersive
20 X-ray spectroscopy showed a magnesium and silicate
21 signature compatible with talc."

22 What he's saying is they observed talc
23 particles in the pelvic lymph nodes that were in the
24 5-to-10-micron range of a woman with a history of
25 genital talc use. Are we in agreement on that?

1 A. I agree that it says what you just read. For
2 purposes of time, I'll agree with you she might have
3 used perineal talc, but you have not actually shown me
4 that.

5 Q. The talc particles, the size of them in this
6 study were 5-to-10 microns. Do you agree that's their
7 finding?

8 A. That is their finding.

9 Q. And I'd also like to direct your attention to
10 Exhibit P-SC 56. That's the Health Canada report.

11 Have you seen this assessment?

12 A. Yes.

13 Q. It's been talked about a lot during these
14 proceedings. They say something interesting on page
15 23 in the second paragraph.

16 So when they studied the size of these talcum
17 powder particles, they discovered that the median
18 particle sizes were ranges from 1.7 to 2 microns.

19 See where they found that right in the middle
20 of that paragraph? The overall range was anywhere
21 from half a micron to 8 microns, but the median range
22 was 1.7 to 2 microns.

23 Is that a fair reading of that?

24 A. Yes.

25 Q. Here is where I'm going with all that. For

1 purposes of reference, a human hair is about 50
2 microns in diameter. Right?

3 A. I have no idea.

4 Q. You can Google it. It will say that I promise.

5 A. I don't have my phone.

6 Q. Here is the point. These talc particles that
7 the women are sprinkling on their external genitalia
8 are extremely small fractions of the diameter of a
9 human hair. Would you agree with that?

10 A. I'll go with you on this.

11 Q. The reason I'm saying that's important is
12 because with each application, a woman is pouring
13 millions, perhaps billions of talc particles on her
14 genitals. Right?

15 MR. WILLIAMS: Assumes facts. Lacks
16 foundation.

17 THE COURT: Sustained.

18 BY MR. DEARING:

19 Q. Knowing now what the size of these particles
20 are, is it still your opinion that this closed system
21 prevents talcum powder particles from entering the
22 vagina?

23 MR. WILLIAMS: Same objection.

24 THE COURT: Well, assuming that the size is as
25 reflected in this report -- now ask your question.

1 BY MR. DEARING:

2 Q. Assuming that the size is as reflected in this
3 Health Canada report and this lymph node study by Dr.
4 Cramer and Dr. Godleski, is it still your opinion that
5 talc particles cannot enter -- that talcum powder
6 placed on the external genitalia cannot enter the
7 vagina?

8 THE COURT: I'm not sure this is where the
9 size came from. Did it come from Cramer?

10 MR. DEARING: This is Health Canada.

11 THE COURT: I'm confused. Why don't you start
12 your question again.

13 Q. My question was: Now that you had an
14 opportunity to review Dr. Cramer and Dr. Goldleskit's
15 lymph node study where they identify the size of
16 particles they found and --

17 THE COURT: I don't think that's fair to say
18 now that she reviewed the study. She said she didn't.
19 Ask the question as presented and the excerpt you had,
20 assuming that to be the case.

21 MR. DEARING: Okay.

22 Q. Can we go back to the Health Canada, please.

23 Assuming that these measurements are accurate
24 and the median particle size of cosmetic talc is 1.7
25 to 2 microns. Is it still your opinion that these

1 talc particles cannot enter the vagina after they have
2 been applied to the external genitalia?

3 A. So two things: One, I believe you are
4 misstating my earlier testimony where you asked me if
5 it was possible, after the perineal application of
6 talc, if a woman has sex, could a talc particle get
7 dragged into the vagina, and I said I think that's
8 possible.

9 And, two, nothing that you have presented to
10 me with these two papers or the IARC monograph section
11 that we just saw changes the opinions in my report or
12 that I gave at deposition or that I have given here
13 this morning.

14 Q. Okay. Is it your testimony that talcum powder
15 applied to the external genitalia cannot enter the
16 vagina just through normal movements throughout the
17 day that a woman might make?

18 A. I do not believe that it does, sir, and I do not
19 know of any study that shows me that particulate
20 matter applied to the external genitalia moves into
21 the vagina with normal activity.

22 Q. Is it your opinion that intercourse is the only
23 way that talc applied externally can get into the
24 vagina?

25 A. So I would say that any talc or particulate

1 that's placed on the external genitalia, if you then
2 convert that external exam into an internal exam by
3 entering the vagina with a substance, either
4 intercourse or speculum or your fingers, that would be
5 a vehicle by which the talc could be dragged in.

6 Short of that, where you are moving from an
7 external application without actually doing some sort
8 of internal penetrance into the vagina, I do not
9 believe that the talc gets into the vagina.

10 Q. So are you saying that the author of the FDA
11 statement we read a minute ago, who used the word
12 "indisputable" and the scientists at IARC just got
13 that wrong; that perineally-applied talcum powder
14 can't enter the vagina?

15 A. So IARC actually says in the talc monograph that
16 the evidence for migration is weak. So I'm not
17 disagreeing with that. The statement by the FDA that
18 migration is indisputable, I don't honestly know where
19 that comes from. And from my research, I don't see
20 any evidence of what we have been talking about here
21 all morning long.

22 Q. Would you agree that studies that suggest that
23 the perineally-applied talcum powder can enter the
24 vagina and migrate to the ovaries? Would you agree
25 that by concluding that it can migrate, they are

1 presuming that it can enter the vagina from the
2 external genitalia?

3 MR. WILLIAMS: Calls for speculation.

4 THE COURT: I'm not even sure what the
5 question asked. Could you rephrase the question.

6 MR. DEARING: Sure.

7 Q. We talked about some studies that opine that
8 perineally-applied talcum powder can migrate to the
9 ovaries. But not many of the studies say it can get
10 from the outside of the vagina to the inside of the
11 vagina.

12 My question is: Based on your reading of
13 those studies, isn't it presumed by those authors that
14 it can get from the outside of the vagina to the
15 inside of the vagina before it migrates?

16 A. I think that's their hypothesis. But no one has
17 any data. So to actually I think correct what you
18 just said, I think you said not many studies show that
19 it gets from the perineum to the vagina when, in fact,
20 there are no studies that show that.

21 So I think the hypothesis is that it must get
22 from the outside, i.e., the external genitalia to the
23 vagina in order to again further migrate to the
24 ovaries.

25 Q. Is the reason you are not willing to accept the

1 proposition that externally-applied talc can get
2 inside absent being forced in there by the way that
3 you have described, is the reason that's your position
4 because there are no studies that show that talcum
5 powder applied to the outside of the vagina can get to
6 the inside of the vagina?

7 A. It's not simply that. It's also that the female
8 genitalia in toto, starting with the lower genital
9 tract and the labia minora, women are not an open
10 conduit. When we go to the ocean and swim in the
11 ocean, you don't get out of the water and have a big
12 gush of ocean water come out of your vagina. It's not
13 an open system. That's not what it is. It's only an
14 open system when we separate the labia and put
15 something physically into the vagina to expand it.

16 So it's not just that there is not a study.
17 It's my experience as a gynecologist, as a GYN
18 oncologist, and honestly as a woman.

19 Q. Are you aware that several Johnson & Johnson
20 experts have affirmed that particles can migrate from
21 the perineum to the ovaries?

22 A. What do you mean by "affirm"?

23 Q. Doctor Michael Birrer, are you familiar with
24 him?

25 MR. WILLIAMS: Objection. Relevance. It's

1 not before the Court.

2 BY MR. DEARING:

3 Q. Doctor Birrer is an expert in the MDL. He
4 offered a report in this case. His opinions are
5 before the Court.

6 MR. WILLIAMS: I'm waiting to see what they
7 read from.

8 THE COURT: I'll wait too.

9 MR. DEARING: I was going to offer opinions
10 from other proceedings from that expert on this topic.

11 MS. O'DELL: Your Honor, if the issue is
12 testimony from a state court case, certainly in the
13 examination of Dr. Longo, I think the entire
14 examination essentially was reading testimony from
15 other proceedings. So I think it is certainly in
16 keeping with that examination.

17 MR. WILLIAMS: The difference --

18 THE COURT: It was Dr. Longo as the witness
19 reading his prior testimony. We're talking about
20 presenting her with testimony of another expert that
21 is not her, and what that person said and trying to
22 cross her about that. Presenting a witness on the
23 stand, an expert with his own testimony is absolutely
24 permissible. That's not what we have here. If he
25 presented testimony from her in another case, that

1 would be fine.

2 MS. O'DELL: I understand.

3 MR. DEARING: Okay.

4 BY MR. DEARING:

5 Q. Can you turn your attention to Plaintiffs'
6 Exhibit 14. This is Blaustein's "Pathology of the
7 Female Genital Tract." Are you familiar with this
8 textbook?

9 A. I'm not sure I'm familiar with that edition, but
10 I am familiar with one of the editions.

11 Q. This is the most current edition, the 6th
12 Edition.

13 A. I know I don't have that.

14 Q. If you look in the 6th Edition on page 681 --
15 (Pause.)

16 A. Okay.

17 Q. This is in Chapter 14. This is the textbook,
18 incidentally, the primary editor is Dr. Robert Kurman.
19 Do you know Dr. Kurman?

20 A. Not personally.

21 Q. You know he is an expert for Johnson & Johnson
22 in this litigation. Right?

23 A. Yes.

24 Q. If you turn to Chapter 14, the title of this
25 chapter is "Surface Epithelial Tumors of the Ovary."

1 That's what we are talking about, right, ovarian
2 cancers?

3 A. Yes.

4 Q. If you turn to page 681, in the section,
5 "Reproductive Factors" he talks about several things.
6 Then he talked about -- he also talks about
7 "surgically induced protective factors that include
8 hysterectomy, tubal ligation, and bilateral salpingo
9 oophorectomy."

10 Doctor, I know you are not fond of the term
11 "protective factors," but you know what he's talking
12 about are factors reducing a woman's risk of getting
13 ovarian cancer?

14 A. Ovarian cancer has been shown to be at a
15 decreased incidence in women with some of these
16 factors. But I would offer that the literature on
17 hysterectomy is inconsistent. I would agree with
18 tubal ligation and bilateral salpingo oophorectomy.

19 Q. So what Dr. Kurman writes is that,

20 "In addition, hysterectomy and tubal ligation
21 prevent the introduction of a variety of potential
22 environmental carcinogens from entering the peritoneal
23 cavity and thereby coming into contact with tubal and
24 ovarian tissue."

25 Doctor, do you agree with me that what Dr.

1 Kurman is saying, if you close off the fallopian
2 tubes, it protects a woman from environmental
3 exposures that make it into the vagina? Right?

4 A. I think you might want to -- that make it into
5 the vagina?

6 Q. By closing off the fallopian tube, what he is
7 saying here is that you are protecting the woman from
8 environmental carcinogens. Environmental carcinogens
9 means carcinogens outside of the body that are getting
10 into the vagina. Right? That is what he is talking
11 about, and then into the reproductive tract.

12 A. So that's a hypothesis. And there isn't a
13 single citation there for that statement. There is
14 some other literature, specifically, on tubal
15 ligations and why tubal ligations may actually reduce
16 the risk of developing ovarian cancer other than it
17 simply being due to retrograde migration.

18 Q. Okay. You say this is a hypothesis. But this
19 is the explanation he is offering in a well-recognized
20 textbook for medical students and residents. Right?

21 A. Hypotheses exist in well-recognized textbooks
22 all the time. That's not a statement of fact and
23 there is no citation there.

24 Q. Okay. While I have this book open, I want to
25 point to some other things that I want to talk about

1 in a few minutes.

2 The very next page in this chapter he talks
3 about inflammation. Do you see that section on
4 inflammation that I've marked?

5 A. Yes.

6 Q. It says:

7 "It has been suggested that inflammation
8 potentially incited by ovulation-induced surface
9 damage, by retrograde menstruation, induced
10 salpingitis, or by the introduction of foreign
11 material through the vagina and uterine cavity plays
12 an important role in ovarian carcinogenesis."

13 Did I read that correctly?

14 A. Yes, you did.

15 Q. So Dr. Kurman is suggesting there is that --
16 there are suggestions among the gynecologic community
17 and pathologic community that inflammation can occur
18 because of the introduction of foreign material
19 through the vagina and uterine cavity, and that it
20 plays an important role in ovarian carcinogenesis. Do
21 you agree with me that is what he is trying to
22 explain?

23 A. Well, I agree that, again, he is putting forth
24 that hypothesis. But, in particular, for the
25 component of the sentence that refers to the

1 migration, again, there is no citation. And he even
2 uses the word "suggested." Suggestion is a
3 hypothesis. That's not primary science.

4 Q. While I'm on this page, the very next section
5 says "other risk factors" and it reads:

6 "Other potential risk factors have been
7 studied, but associations with ovarian cancer risk are
8 weak or inconclusive. These include the body mass
9 index."

10 That's the obesity you were talking about
11 before?

12 A. Yes.

13 Q. (Reading continued.)

14 "Age at birth of first child, breastfeeding,
15 weight, diet, talc, smoking, certain types of viral
16 infections in childhood, and ionized radiation."

17 Do you agree that those with the exception of
18 talc are recognized risk factors for ovarian cancer?

19 A. All of those factors have been evaluated in the
20 literature at one point or another, and there have
21 been different calculated odds ratios, yes.

22 Q. I have a whole other section on risk factors.

23 THE COURT: If you are going to a new section,
24 we'll break now for lunch.

25 45 minutes, please.

1 THE DEPUTY CLERK: All rise.
2 (The luncheon recess is taken.)
3 (Continued on the next page.)

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1 **A F T E R N O O N S E S S I O N**

2
3 (In open court.)

4 THE DEPUTY CLERK: All rise.

5 THE COURT: Thank you.

6
7 **CHERYL C. SAENZ**, resumed.

8
9 CROSS-EXAMINATION (Continued)

10 BY MR. DEARING:

11 Q. Dr. Saenz, where we left off, I was just showing
12 you where Dr. Robert Kurman, one of Johnson &
13 Johnson's experts in this litigation, identified in
14 his textbook perineal talc use as a potential risk
15 factor in ovarian cancer.

16 You said one example of a way talcum powder
17 can get from the outside of the vagina to the inside
18 is intercourse, or some forceful mechanisms. I don't
19 think those were your words, but that's what I
20 understood you to say.

21 Would that also include tampon insertion?

22 A. I think I used the word penetration. So
23 theoretically, yes. And as we actually saw earlier
24 this morning, we know that talc can be on diaphragms
25 and women put those in. That would be a way of

1 getting it into the vagina as well, so Blaustein's
2 Pathology book is not the only book that suggests a
3 woman's reproductive tract is an open conduit.

4 I would like to show you what is marked as
5 Exhibit P-SC 34. This is a medical illustration. Are
6 you familiar with Netter?

7 A. Not in the last 20 years have I looked at
8 Netter.

9 Q. Netter describes the vagina from the Latin,
10 "literally sheath or scabbard, serves as the portal to
11 the internal female reproductive tract and the route
12 of egress for the fetus during delivery."

13 So Dr. Netter describes it as a portal from
14 the outside world to the inside.

15 Are you familiar with Baggish and Karram?

16 THE COURT: Was there a question? You just
17 read from that book but you didn't ask anything.

18 Q. Do you agree the vagina serves as a portal from
19 the outside world to the inside of a woman's
20 reproductive tract?

21 A. The vagina serves as an organ that is in between
22 the outside world, i.e., the external genitalia, and
23 the upper genital tract, and it is an organ that
24 babies pass through as they are born.

25 Q. Some of these questions seem elementary, and I

1 apologize for that, but I want to make sure that we
2 are clear on what your testimony is.

3 Are you familiar with the Atlas of Pelvic
4 Anatomy and Gynecological Surgery?

5 A. No.

6 Q. By Baggish and Karram. This is PSC 33?

7 A. No.

8 Q. This is a current textbook. If you turn to the
9 chapter on the anatomy of the vagina, the first
10 sentence says:

11 "The vagina is a potential space that connects
12 the lower portion of the uterus, cervix to the outside
13 environment."

14 Do you agree with that statement?

15 A. I agree with it. But just so that we are sure
16 what we are saying, "potential space" means it is not
17 an open space. So that actually substantiates what I
18 have testified to before, which is that the walls of
19 the vagina are collapsed on themselves; and the vagina
20 is part of the lower genital tract. That's what that
21 sentence says.

22 Q. It's not your testimony today all vaginas are
23 the same, they are just alike. I can't believe I'm
24 asking this question.

25 A. I think you need to specify a little bit more

1 what you are asking me.

2 Q. Are you familiar with Crum's Diagnostic
3 Gynecologic and Obstetric Pathology?

4 A. No.

5 Q. This is the 2018 version of this textbook. If
6 you turn to Chapter 24, entitled "Assessing Pelvic
7 Epithelial Cancer Risk."

8 THE COURT: Do you have an exhibit number?

9 MR. DEARING: S 35.

10 Q. Chapter 24 is entitled, "Assessing Pelvic
11 Epithelial Cancer Risk and Intercepting Early
12 Malignancy."

13 A. Can you show me the title, please.

14 Q. Sure.

15 A. Thank you.

16 Q. There is a section on talc exposure here. What
17 it says is:

18 "Talc placed on the perineum may enter the
19 vagina and ascend to the upper genital tract.
20 Structurally similar to asbestos, there is theoretical
21 concern talc may potentially increase ovarian cancer
22 risk."

23 Do you agree with that statement that talc
24 placed on the perineum may enter the vagina and ascend
25 to the upper genital tract?

1 A. No, and there is no citation there. That's just
2 a statement. Additionally, the second sentence that
3 you read had in it the word "theoretical" which is a
4 hypothesis.

5 Q. The word theoretical had to do with what happens
6 to the tissue when the talc ascends. That wasn't
7 applying to whether it can ascend. Right?

8 A. No. The word "theoretical" applied to whether
9 or not talc is associated with increased risk of
10 developing ovarian cancer.

11 Q. The first sentence that I read says:

12 "Talc placed on the perineum may enter the
13 vagina and ascend to the upper genital tract."

14 Do you agree with that statement?

15 A. No.

16 Q. So what I'm hearing you say is absent some
17 forced penetration, there is no way for talcum powder
18 particles to enter the vagina from the external
19 genitalia. Is that what you are saying?

20 MR. WILLIAMS: Misstates testimony, your
21 Honor.

22 MR. DEARING: I'm asking her if that is her
23 testimony.

24 THE COURT: Do you understand the question?

25 THE WITNESS: Yes, your Honor.

1 THE COURT: Can you answer it?

2 THE WITNESS: Yes, your Honor.

3 THE COURT: Go ahead.

4 THE WITNESS: Sir, I never used the word
5 "forced." I said that there must be something that
6 actually penetrates into the vagina if there is going
7 to be the possibility of carrying a talc particle with
8 it from the external genitalia into the vagina.
9 "Forced," is your adjective.

10 BY MR. DEARING:

11 Q. I'm trying to understand what you mean by
12 "penetrate." Can you explain in layman's terms what
13 you are talking about.

14 A. Put into.

15 Q. Are you saying if the talc particles are not put
16 into the vagina, they can't get in there just through
17 natural activities?

18 A. What do you mean by "natural activities"?

19 Q. Walking, sleeping, running, sitting.

20 A. I do not believe that any of those activities
21 would carry a talc particle from the external
22 genitalia into the vagina, and I do not know of any
23 studies that would support that hypothesis.

24 Q. Is it your opinion talcum powder is safe to use
25 on the perineum for women?

1 A. Yes.

2 Q. If talcum powder was 50 percent asbestos, would
3 you still say it was safe for women to use?

4 A. If it were 50 percent asbestos?

5 Q. Yes.

6 A. No.

7 Q. You would not say it's safe to use?

8 A. I don't know what the constituent particles are
9 within talcum powder. But if you are giving me a
10 hypothetical, I would say I wouldn't advocate for
11 anybody to put anything that's 50 percent asbestos on
12 their body. But the literature, as it stands now on
13 this particular topic, does not support a causal
14 association between perineal application of talc and
15 the development of ovarian cancer.

16 Q. So is the reason that you will not recommend
17 someone to use powder that was 50 percent asbestos on
18 the perineum is because it might get into the
19 reproductive tract?

20 A. No. I wouldn't recommend anybody use anything
21 that's 50 percent asbestos in any aspect of their
22 life.

23 Q. I asked a minute ago whether all vaginas are
24 designed -- or whether they all are anatomically the
25 same. I don't remember what you said. I'm sorry.

1 A. I asked you to define that a little better.

2 Q. Are they all anatomically shaped the same?

3 A. No.

4 Q. Would you agree some are more open than others?

5 A. Open to what?

6 Q. Just open, like not overlapping where the labia
7 is not overlapping.

8 A. No, the labia are opposed.

9 Q. I would like to show you my least favorite
10 study, that's PSC 31. This is a study by a British
11 scientist. It's called Lloyd from 2005. Are you
12 familiar with it.

13 A. No.

14 Q. So you get a sense of what this study was about,
15 they were actually measuring -- they were taking
16 dynamics, measurements of external genitalia of women,
17 and it was to benefit surgeons contemplating cosmetic
18 surgery for patients or other types of surgery. But
19 it was a population of 50 premenopausal women having
20 gynecological procedures not involving the external
21 genitalia and under general anesthetic.

22 So they are very graphic in this study to
23 point out several anatomic features of the normal
24 vagina.

25 Can you go to the next page and pull up that

1 diagram. This is the diagram they chose to use to
2 show how they were measuring the anatomic points of
3 the vagina. Would you agree with me that's not
4 overlapping labia at all?

5 A. What position are these women in?

6 MR. DEARING: Well, can you zoom back out.
7 Can you go to the results section.

8 Q. I'm not sure what position that woman was in,
9 but they were using it to show what they were
10 measuring, what dimensions, top to bottom.

11 Does it make a difference?

12 A. Absolutely.

13 Q. Explain that to me.

14 A. If they are lying supine, and I assume they are
15 because these women were under general anesthesia, and
16 their legs are up in a lithotomy position, that's
17 going to extend their external genitalia and
18 physically pull them apart even without somebody
19 separating them with their fingers.

20 So that is not the way that the external
21 genitalia rest on each other in a woman that's sitting
22 or standing.

23 Q. Wouldn't you agree with me there are certain
24 movements in everyday life of a woman that would allow
25 for that separation you are talking about, maybe not

1 to the extent you are describing, but just some
2 separation just in every day movement?

3 A. What types of movements?

4 Q. Running. Wouldn't that cause some kind of
5 separation?

6 A. No.

7 Q. What about sleeping with your legs apart?

8 A. No.

9 Q. What about sleeping with a pillow between your
10 knees?

11 A. No.

12 Q. Is it your testimony under no circumstance does
13 a vagina open significantly enough for talcum powder
14 particles to get in, unless they are being penetrated,
15 to use your words?

16 A. Or if, as I suspect in this diagram, this photo
17 you just showed, they are in a lithotomy position
18 where their legs are extended, elevated, and the
19 external genitalia are being separated physically.

20 Q. Would you agree with me invasive serous ovarian
21 carcinomas are by far the most common of all the
22 epithelial ovarian cancers?

23 A. Yes.

24 Q. Would you agree with me they make up 80 to
25 90 percent of the epithelial ovarian cancers?

1 A. I think that number is a little high. I would
2 say more in the range of 60 to 70 percent, but there
3 are variances depending on what published study you
4 are looking at.

5 Q. Would you be surprised the NCI Cancer Genome
6 Atlas identified invasive serous ovarian carcinomas as
7 making up 80 to 90 percent of the epithelial ovarian
8 cancers?

9 A. I would need to see the reference for that
10 because I think what that is referring to is specimens
11 that were submitted for the goal of molecular
12 profiling them. So I'm not entirely sure that's
13 reflective of the disease incidence.

14 MR. DEARING: Can you pull up Plaintiffs'
15 Exhibit 51 -- that's not right. That's wrong.

16 It's PSC Saenz 5. It's in your binder.

17 Can you pull up that first paragraph.

18 Q. This is from the National Cancer Institute, and
19 it's from The Cancer Genome Atlas. That's the TCGA.
20 Midway through it says:

21 "Ovarian serous adenocarcinoma, the cancer
22 studied by TCGA, is a type of epithelial ovarian
23 cancer and it accounts for about 90 percent of all
24 ovarian cancers."

25 Do you see that?

1 A. Yes.

2 Q. Do you agree with that statement?

3 A. I think that's fine. I said, depending on what
4 study you are looking at, the rate varies a little
5 bit.

6 Q. Would you agree with me, high grade serous
7 carcinoma is the most aggressive of the epithelial
8 ovarian cancers?

9 A. I need you to define "aggressive." The reason
10 for that is that high grade serous carcinomas are not
11 as chemoresistant as some of the other tumors. So the
12 adjective "aggressive" --

13 Q. How about most likely to metastasize?

14 A. I can't agree with that. I think all the
15 ovarian cancers are likely to metastasize except for
16 perhaps to the same degree the borderline tumors.

17 Q. Would you agree with me the five-year survival
18 rate for invasive serous carcinomas for Stage III and
19 IV is less than 15 percent?

20 A. Five-year survival?

21 Q. For Stage III and IV disease?

22 A. That's not the current statistics, no.

23 Q. Would you agree with me Stage III and IV serous,
24 high grade serous has about an 80 percent recurrence
25 rate?

1 A. Yes.

2 Q. The point I'm trying to make is high grade
3 serous carcinomas are the most common and possibly the
4 most dangerous of the epithelial ovarian cancers.
5 Would you agree?

6 A. No. Again, that's primarily because high grade
7 serous carcinomas -- actually, at least on the first
8 go-around of treatment -- are very sensitive to
9 chemotherapy. So most women with that cancer will
10 actually go into remission for some period of time.
11 They are not as hard to treat as, say, the mucinous or
12 the clear cell histology.

13 Q. With an 80 percent recurrence rate, they are
14 almost impossible to cure, aren't they?

15 A. All of the ovarian cancers, if they are first
16 diagnosed at Stage III and IV are almost impossible to
17 cure.

18 Q. Where I'm going with all of that is you cited
19 the Gertig study and you discussed it earlier in your
20 direct examination. Do you agree with me -- let me
21 back up. In your report, you said you prefer the
22 cohort studies to case-control studies because they
23 were more, I think you used the term, maybe
24 scientifically reliable for something like that.

25 A. I might have said credible because they are not

1 as subject to selection bias and recall bias.

2 Q. And so Gertig was one of the cohort studies you
3 used to support your opinions. Right?

4 A. Gertig was the first cohort that was published
5 in the year 2000, yes.

6 Q. Would you agree with me the Gertig study showed
7 that women who applied talc one-to-six times per week
8 had a statistically significant relative risk or
9 increased risk of 49 percent?

10 A. Can you please show me that table, sir?

11 Q. Certainly.

12 MR. DEARING: Can you pull up PSC Exhibit 51,
13 please. Can you blow up the title and the author.

14 Q. This is the Gertig 2000 study. Right?

15 A. Yes.

16 Q. If you will, look in the bottom of the first
17 column. It states one of the findings, starting with
18 the sentence:

19 "There was a modest elevation in risk for ever
20 talc use and invasive serous ovarian cancer with a
21 multivariate relative risk of 1.40 with a confidence
22 interval of 1.02 to 1.91."

23 That's showing a statistically significant
24 40 percent increased risk for invasive serous ovarian
25 cancer. Right?

1 A. Yes.

2 Q. And then, if you will, turn the page and go down
3 beneath the chart. In the very right-hand corner of
4 that page, they discuss some other relative risks, and
5 what they specifically look at is women who used talc
6 at least once a week, which is essentially the women
7 in this MDL, and it says:

8 "The relative risk for ever talc users less
9 than once a week and one to six times per week were
10 noted 1.29" -- that's for the less than once per week
11 -- "and 1.49 for one to six times per week."

12 Did I read that correctly?

13 A. Yes, you did.

14 Q. So this Gertig study that you relied on that you
15 said is more scientifically reliable than the
16 case-control studies actually says that women who used
17 perineal talc use, at least once a week, have a
18 statistically significant increased -- I'm sorry --
19 have an increased risk of 1.40 -- a 40 percent
20 increased risk. Right?

21 A. Are we going back to the 1.4 or are we
22 discussing the numbers you have up on the marquis
23 right now?

24 Q. Let me back up. The 1.49, you see the
25 confidence interval crosses 1. Does that mean you

1 absolutely should discard the results if the
2 confidence interval crosses 1?

3 A. If the confidence interval crosses 1, it means
4 the finding is not statistically significant, and what
5 that means is that you can't tell that there is really
6 a difference between your study group and your control
7 group.

8 Q. The point is: This Gertig study that you rely
9 on, that you said is scientifically reliable because
10 it's a cohort study and not a case-control study,
11 suggests that for invasive serous carcinomas, the most
12 common type of epithelial ovarian cancers with an
13 80 percent recurrence rate increases a woman's risk by
14 40 percent. Right?

15 A. So, one, I think you are misstating my
16 testimony. I did not say the cohorts were more
17 reliable. I said I think they are more scientifically
18 credible because they are not as subject to the biases
19 of the case-control studies.

20 I also never said I don't find the
21 case-control studies informative. You are correct,
22 that in this Gertig study, which was the 2000
23 publication, there was a statistically significant
24 finding for ever use of perineal talc and an increased
25 risk of serous ovarian cancer.

1 But as we discussed earlier this morning, this
2 study had a follow-up study 10 years later in which
3 this particular finding did not withstand the test of
4 time. So as more women developed ovarian cancer,
5 there was no unique finding in the serous ovarian
6 cancers, which speaks to the likelihood that this was
7 a random finding within the Gertig study because there
8 is no latency in the Gates study.

9 MR. DEARING: Can you pull up slide 10.

10 Q. This is a slide that has been used several
11 times. This was shown to several witnesses already,
12 but I wanted to go over it with you real quickly.

13 This is a summary of the meta-analyses and
14 pooled analyses of the talcum powder ovarian cancer
15 risk. I want to make one observation about it because
16 the Court has seen this quite a bit.

17 Do you agree the forest plot confidence
18 intervals shown on this chart are all statistically
19 significant and that they are all right of 1?

20 A. Yes.

21 Q. Do you also agree these are in somewhat
22 chronological order? But the 2018 studies are at the
23 top. So the more these meta-analyses combine data
24 subjects and the bigger the studies get, the smaller
25 the confidence intervals get. Do you agree with that

1 observation?

2 A. It would appear from the forest plot that that
3 is the case.

4 Q. And what that means, when the confidence
5 interval is shrinking is that there is less and less
6 chance that the results are the product of chance.
7 Right?

8 A. That's correct. That's the definition.

9 Q. And would you agree, based on this forest plot,
10 that the relative risk from these meta-analyses and
11 pooled studies all fall within 1.2 to 1.4?

12 A. Yes.

13 Q. And when you put up a slide earlier today, or
14 Mr. Williams put up a slide, and you were suggesting
15 watching TV and taking Valium and eating processed
16 meat increases the woman's risk of ovarian cancer, the
17 literature on those things is not as robust as the
18 literature on talc and ovarian cancer, is it?

19 MR. WILLIAMS: Objection to the preamble, your
20 Honor. It misstates the evidence.

21 THE COURT: It wasn't exactly the testimony.
22 Those were identified as things, and she explained why
23 they are not precisely risks.

24 We'll go on.

25 BY MR. DEARING:

1 Q. Let's talk about risk factors. As I understand
2 it, your opinion is that there are known risk factors
3 that increase or perhaps decrease the risk of the
4 development of ovarian cancer but genital talc use is
5 not one of them. Is that a fair summary of your
6 opinion?

7 A. Yes.

8 Q. When we're talking about a risk factor, we're
9 talking about some exposure that increases the chance
10 of developing a disease. Right?

11 A. Not always.

12 Q. Well, for purposes of talcum powder and whether
13 talcum powder causes ovarian cancer and the risk
14 factors for ovarian cancer that you talked about, are
15 you referring to when you use the term, "risk factor,"
16 are you referring to exposures that will increase a
17 woman's risk of getting ovarian cancer?

18 A. But not all risk factors are exposures.

19 Q. Okay. Well, that's maybe not a good word then.
20 Is a risk factor something that increases a woman's
21 risk of getting ovarian cancer?

22 A. I would say a risk factor is something that has
23 been identified as being associated with the
24 development of a disease.

25 Q. And you identified several risk factors in your

1 report. I'm not going to go through all of them.

2 You mentioned endometriosis, and you said
3 endometriosis is a risk factor for endometrioid and
4 clear cell carcinoma. Is that accurate?

5 A. Yes.

6 Q. And you said tobacco use is a risk factor for
7 mucinous carcinoma. Right?

8 A. It's weak, but it has been associated with the
9 development of mucinous ovarian carcinoma, yes.

10 Q. You said obesity increases a woman's risk for
11 borderline tumors, clear cell, mucinous and
12 endometrioid. Right?

13 A. Right. Again, that's another weak factor, but it
14 has been associated with the development of those
15 different histologic subtypes.

16 Q. So in identifying endometriosis, smoking and
17 obesity as a risk factor, are you stating that those
18 are things -- that those are biologically plausible
19 contributors to ovarian cancer?

20 In other words, is it biologically plausible
21 that obesity increases a woman's risk of ovarian
22 cancer?

23 A. So I don't know that a biologically plausible
24 mechanism has been attached to the development of
25 ovarian cancer for each and every one of those risk

1 factors.

2 Q. But you are still willing to suggest that
3 obesity is a risk factor for each of those four
4 histologies?

5 A. Yes. That's because the epidemiological
6 literature on that risk factor across case-control
7 studies and cohort studies has found that consistent
8 albeit weak odds ratio.

9 Q. You would agree with me that scientists don't
10 know exactly how obesity increases a woman's risk for
11 ovarian cancer. Right?

12 A. Yes.

13 Q. You cite Olsen, the Olsen study to support your
14 inclusion of obesity in your list of risk factors.
15 It's the Olsen 2013 study. Do you remember that?

16 A. I don't think -- if I recall, and I could be
17 mistaken, I think Olsen is a review article. But if
18 you have it and we can look at it, that would be
19 great.

20 Q. Would you agree you cited it in your report to
21 support your inclusion of obesity in the risk factor
22 list?

23 A. Yes.

24 MR. DEARING: Will you pull up Saenz 2,
25 please.

1 Q. This is a review from an ovarian cancer
2 consortium of about 50 scientists. Right?

3 A. Well, they reference at least 25 different
4 institutions. So I would be guessing. If you counted
5 all those authors, I'll give it to you.

6 Q. I have not. I was guessing.

7 A. Okay.

8 Q. I want to look at the results section, which is
9 page 5, and here is where they identified the results
10 having stratified the different histologies. What
11 they say is that the odds ratio for borderline tumors
12 was 1.24. Clear cell was 1.06 --

13 A. Where are you, sir?

14 Q. Let me come back to this study and I'll find the
15 data when I have more time to look at that.

16 Do you have any recollection as to whether the
17 odds ratio for obesity in this Olsen study or any of
18 the studies you have seen rise to the level of 1.49 as
19 was identified in the last cohort study we just
20 discussed for serous invasive?

21 A. So the relative risk in the Gertig study that
22 was statistically significant was for ever versus
23 never use and it was not 1.49. It was 1.40.

24 Q. I'm sorry. I misspoke.

25 A. And my read on the literature on obesity and the

1 literature that I've cited is that the relative risk
2 on obesity is in the range of about 1.2 to 1.3. But
3 if you have something showing me that there is
4 something higher, I would be happy to look at it.

5 Q. That's exactly right. That was my point.

6 You testified earlier about genetic mutations,
7 and probably the most influential risk factor I
8 suppose is a genetic predisposition of ovarian cancer.
9 Do you agree?

10 A. Yes.

11 Q. Would you also agree genetic mutations only make
12 up about 1 percent of diagnosed ovarian cancers?

13 A. Epithelial ovarian cancers?

14 Q. Yes.

15 A. No, I would not agree with that at all.

16 Q. Would you agree only about one in 500 women test
17 positive for the BRCA gene?

18 A. In the general population?

19 Q. In the general population, yes.

20 A. The data on that is quite variable because it
21 depends upon identifying certain founder populations.
22 For example, Ashkenazi Jewish women have the incidence
23 of 11 percent for being positive for BRCA 1 and 2
24 mutations. There is a known Polish mutation, a French
25 Canadian mutation. So I don't actually look at

1 general population statistics. I think the more
2 useful metric is to look at women who have been
3 diagnosed with ovarian cancer and what percentage of
4 those women are found to be positive for a genetic
5 mutation that has been inherited.

6 Q. So that I'm clear, is it your opinion that talc
7 may be a risk factor for ovarian cancer, or it's
8 absolutely no way it's not possible, it's not a risk
9 factor for ovarian cancer?

10 A. So based on the current state of the science, it
11 is not a risk factor for the development of ovarian
12 cancer.

13 Q. Would you agree with me many reputable
14 scientists disagree with you on that; many different
15 reputable scientists and researchers do believe
16 perineal talc use increases a woman's risk for ovarian
17 cancer?

18 A. I know even based on this hearing that there are
19 people that disagree with that opinion, but I don't
20 think that they are looking at the literature
21 correctly because it would not support the position
22 that talc is a risk factor for developing ovarian
23 cancer.

24 Q. It's been discussed in this hearing there are
25 some institutions that failed to list talc as a risk

1 factor for ovarian cancer. I'm sure you are familiar
2 with some of them. You talked about some earlier.
3 Right? Organizations, I should say.

4 A. I still wouldn't characterize it as they failed
5 to list it because inherent in that statement is a
6 bias that they are not doing what they are supposed to
7 do. They don't list it.

8 Q. Okay. Would you also agree with me there are
9 academic institutions that do list talc as a risk
10 factor for ovarian cancer?

11 A. There may be but I don't know what they are
12 basing that determination on.

13 Q. You've been an attending physician at the
14 University of California San Diego for about 20 years.
15 Right?

16 A. Almost 21.

17 Q. And, specifically, you work at the Moores Cancer
18 Center at UCC San Diego, right?

19 A. That's where my clinic and academic offices are.

20 Q. I took this quote from your report. We can look
21 it up if you like.

22 The Moore Cancer Center, you described it as a
23 comprehensive high quality patient center care.
24 That's how you described the care that's being offered
25 there. Would you agree with that description?

1 A. Well, an NCI designated comprehensive cancer
2 center.

3 Q. Part of that comprehensive high quality care is
4 to give information to the public when they are
5 curious about certain topics on cancer. Right?

6 A. Yes.

7 Q. They maintain a website to do that, right?

8 A. UCSD and the Moores Cancer Center maintains
9 several different websites.

10 Q. The website offered by Moores Cancer Center, it
11 offers current accurate information about risk factors
12 pertaining to ovarian cancer. Right?

13 A. I don't know the answer to that.

14 MR. DEARING: Well, can you pull up slide PSC
15 3, please. Actually it's slide 1.

16 Q. This is from the website from U.C. San Diego
17 Health and the Moores Cancer Center.

18 If you click on, "What Do You Know About
19 Reproductive Cancers?", they have you take a little
20 test. I thought it was interesting, the answer to No.
21 6.

22 MR. DEARING: Can you blow up the right side
23 of that slide.

24 Q. The answer to No. 6, and the question is in the
25 answer:

1 "A woman's lifetime chance of getting invasive
2 ovarian cancer is about one in 78. What are the
3 factors that put a woman at risk for this cancer?"

4 They identify several of the risk factors:
5 Family history, age, child bearing, personal history.
6 Then it goes on to name some others. It says:

7 "Other possible factors include taking
8 fertility medicines. These may slightly increase the
9 risk of ovarian cancer. Talc may be a risk factor.
10 Some studies suggest that women who use talc in the
11 genital area for many years may be at risk. Hormone
12 therapy may also raise the risk."

13 The last sentence says:

14 "Having one or more risk factors mentioned
15 here does not mean that a women is sure to develop
16 ovarian cancer, but the chance may be higher than
17 average."

18 The fact that U.C. San Diego and Moores Center
19 put this information about risk factors and this
20 information about talc specifically in their website
21 means that they have a different position on talc and
22 risk factors than you do. Correct?

23 A. No, that's not correct.

24 Q. Do you agree with the statement that's up there
25 that talc may be a risk factor?

1 A. No, I do not.

2 Q. If the institution is putting this information
3 out there that says talc may be a risk factor and you
4 are saying you don't believe that, don't you have a
5 difference of opinion here?

6 A. May I explain?

7 Q. Sure.

8 A. So the information that is posted on the patient
9 friendly websites, if you will, is posted by the
10 marketing and communications department. They do not
11 consult any of the physicians at UCSD. They contract
12 with a third-party vendor and post what that
13 third-party vendor posts at multiple institutions
14 across the country.

15 Q. Are you telling me there is no one at Moores
16 Cancer Center that monitors what goes on their website
17 to the public?

18 A. That's what I'm telling you.

19 Q. That seems very risky.

20 A. I don't disagree with you. It doesn't make me
21 happy but it is the way the marketing and
22 communications department functions.

23 Q. Apparently, there is at least one medical
24 physician and one nurse who oversees it, right; an
25 online medical reviewer, Dr. Richard Lo Cicero. Do

1 you see that?

2 A. He's not a UCSD physician.

3 Q. Do you know him?

4 A. I don't know him. He is not in our division.
5 He is not in the Moores Cancer Center.

6 MR. DEARING: Will you pull up PSC Saenz 8,
7 please.

8 Q. Are you familiar -- this is a publication from
9 Gynecologic Oncology. Do you subscribe to this
10 journal Gynecologic Oncology?

11 A. Online.

12 Q. Do you recall if you have ever seen this -- this
13 is called "Opportunities and Challenges in Ovarian
14 Cancer Research," a perspective from the 11th ovarian
15 cancer action HHMT forum in Lake Como in March 2007.
16 Do you remember ever seeing that?

17 A. No.

18 Q. If you will, scroll down to the first page, the
19 abstract. What this is, this is 50 or more of the
20 world's leading ovarian cancer researchers --

21 A. Can you say that again?

22 Q. This is a list of the coordinators of this
23 conference. One is then is Dr. Jeff Boyd, who is a
24 defense expert. At this conference there were 50 or
25 more leading researchers and --

1 A. I don't believe there are 50 authors, sir.

2 Q. I'm having a hard time seeing it up there. So
3 let me look in my binder real quick.

4 (Pause.)

5 So on page 656, in the bottom right-hand
6 corner, this is a list of the attendees. There are
7 probably more than 50, I was estimating.

8 A. That's not necessarily who authored this paper.
9 Right?

10 Q. I agree with you.

11 These are the attendees that are attending
12 this consortium. Okay?

13 A. Okay.

14 Q. I suspect the authors are listed on the next
15 page, and there are eight or nine of them. See them
16 on the right?

17 A. Yes.

18 Q. What they say, if you go to the first page,
19 second paragraph in the right column:

20 "A combination of demographic, reproductive
21 and environmental risk factors might be used to
22 develop a model that would more accurately predict
23 risk," when they are talking about risk of ovarian
24 cancer.

25 "One preliminary algorithm using seven risk

1 factors: age over 45, long-term genital talc use,
2 family risk of ovarian cancer, or early onset breast
3 cancer," and some other things, "showed that women
4 with six to seven of these events have an odds ratio
5 of 7.59."

6 The point I'm making here is this consortium
7 back in 2007 seem to be identifying long-term genital
8 talc use as a risk factor for ovarian cancer. Would
9 you agree?

10 A. Well, they put that into an algorithm that they
11 created in 2007. But as we sit here now, in 2019, no
12 such algorithm exists in clinical practice.

13 Q. My point is all the way back in 2007, talc was
14 being discussed as a risk factor for ovarian cancer.
15 Do you agree?

16 A. Talc is being discussed as a risk factor for
17 ovarian cancer since 1982, but that doesn't mean that
18 it causes it. In fact, after this was published is
19 when the Gates 2010 study came out. So the fact that
20 this was proposed in 2007, I haven't stated that it
21 wasn't being discussed back then. But we're now
22 12 years into the future, and there is no algorithm in
23 clinical practice that plugs genital use of talcum
24 powder into calculating a woman's risk of developing
25 ovarian cancer.

1 Q. Okay. But there are many institutions and
2 consortiums like this that continue to include
3 perineal use of talcum powder a risk factor for
4 ovarian cancer in their general discussions. Right?

5 A. I don't know what you are referencing.

6 Q. You offered some opinions about causation and
7 inflammation on direct. I want to ask you a couple of
8 questions about that.

9 I think you said there was no evidence that
10 inflammation contributes to ovarian cancer, and to say
11 that you were relying on the Merritt study. Am I
12 recalling that correctly?

13 A. What I believe I said is that there is no data
14 that chronic inflammation leads to the development of
15 ovarian cancer. Merritt is only one of the studies
16 that I looked at to support my opinion.

17 Q. Would you agree that inflammation does play a
18 role in the initiation and development of many types
19 of cancers?

20 A. Not ovarian cancer.

21 Q. But it does for others?

22 A. It does for certain cancers such as colon
23 cancer.

24 Q. Are you familiar with the Savant 2018 study?

25 A. I think I've seen a review article by them.

1 MR. DEARING: Would you pull up PSC 115,
2 please.

3 Q. Does this study look familiar?

4 A. It's not a study. It's a review article. It's
5 not primary science.

6 Q. Does this review article look familiar?

7 A. Yes.

8 Q. Would you look at the abstract, please.

9 First of all, this is June 14th, 2018,
10 actually published July 30th, 2018.

11 Do you see that?

12 A. Yes.

13 Q. It's by three scientists from the University of
14 Indiana.

15 MR. DEARING: And if you would highlight the
16 abstract, please.

17 Q. The first sentence of the abstract reads:

18 "Inflammation plays a role in the initiation
19 and development of many types of cancers, including
20 epithelial ovarian cancer, in high grade serous
21 ovarian cancer, a type of epithelial ovarian cancer."

22 Do you see that?

23 A. I see that they wrote that.

24 Q. Do you disagree with them?

25 A. I don't see any citations for that. I don't see

1 this is as primary science, and I don't know of any
2 primary science that supports that chronic
3 inflammation initiates ovarian cancer.

4 Q. Would you go to the next page, please, top of
5 the page, second line down, the sentence starts:

6 "Chronic inflammation is an important risk
7 factor associated with epithelial ovarian cancer in
8 high grade serous ovarian cancer, the most malignant
9 subtype of epithelial ovarian cancers."

10 Do you see that?

11 A. I do see that.

12 Q. You still disagree with them?

13 A. Yes. And there is no citation.

14 Q. Would you go to page 3 of 30, first sentence of
15 that inflammation section, it says:

16 "Amongst other factors, such as hereditary,
17 environmental, and lifestyle, inflammation emerges as
18 an important risk factor for epithelial ovarian
19 cancer."

20 Still disagree with them?

21 A. Again, sir, there is no citation. This is a
22 statement that's made without referring to any primary
23 science.

24 Q. Let's look at some primary science.

25 Would you go to the next page, please, 2.2,

1 where it says "infection."

2 It says:

3 "Pelvic inflammatory disorder is the infection
4 of the female reproductive organs, like the cervix,
5 uterus, fallopian tubes, and ovaries, it is a
6 significant risk factor for ovarian cancer."

7 You disagree with that?

8 A. There is literature to show pelvic inflammatory
9 disease, one episode specifically does not increase a
10 woman's risk of developing ovarian cancer. There is
11 literature to also show that with two or more episodes
12 of PID, that there is an increased risk specifically
13 for borderline ovarian cancers.

14 So I don't just blanket disagree with that
15 statement because there is some literature to support
16 it in terms of women with repeated episodes of PID but
17 for a very specific type of ovarian cancer.

18 Q. Okay. I know this question is obvious, but
19 pelvic inflammatory disorder or PID is an inflammatory
20 condition. Right?

21 A. It's an infection that leads to inflammation,
22 correct.

23 Q. In the next paragraph it discusses other sources
24 of inflammation, and it says:

25 "The other causes" -- let's go back up to

1 infection. It cites studies there in the next few
2 lines. Since we are in agreement about that, I think
3 I'm just going to move on.

4 Now, in the next section "other sources of
5 inflammation," it says, quote:

6 "The other causes of inflammation in the
7 ovaries and/or fallopian tubes are endometriosis,
8 obesity, polycystic ovarian syndrome and talc
9 exposure."

10 Do you believe that endometriosis causes an
11 inflammatory reaction that may lead to some type of
12 ovarian cancer?

13 A. So I think that endometriosis as a risk factor
14 for developing ovarian cancer is a really complex
15 issue. I don't think it's necessarily a yes or no
16 answer because endometriosis in and of itself, which
17 involves the implanting of endometrial glands on other
18 organs in the pelvis, that implanting of the glands
19 can cause a localized inflammatory reaction.

20 But the actual precursor lesion for the
21 development of the cancer seems to be that those
22 endometrial cells start to develop atypia which is a
23 precursor lesion of the cancer itself and it's also
24 found within the uterus within the endometrial cavity
25 as endometrial cancer is developing.

1 So I think it's a complex issue.

2 Q. The sort of misplacement of those endometrial
3 cells causes an inflammatory response, doesn't it?

4 A. It can, but it's not necessarily the cancer is
5 developing from that inflammatory response as much as
6 those endometrial cells are becoming precancerous
7 themselves.

8 Q. These authors also ascribe an inflammatory
9 process to the obesity risk factor, and it's a lengthy
10 explanation I don't think we really have time for.

11 In the next paragraph they say:

12 "Obese women have higher risks of epithelial
13 ovarian cancer and high grade serous carcinoma and
14 pro-inflammatory cytokines are associated with higher
15 body mass index levels."

16 Do you agree inflammation may play a role in
17 the risk factor of obesity?

18 A. I don't think that has been worked out. I think
19 that's a hypothesis.

20 Q. These authors also say that polycystic ovarian
21 syndrome is a risk factor and a source of
22 inflammation. Do you agree with that?

23 A. In and of itself I don't know, nor do I
24 necessarily agree that polycystic ovarian syndrome is
25 a risk factor for ovarian cancer. I think that gets

1 subsumed into women that are nulliparous. PCOS is a
2 cause of infertility, and we know that infertility is
3 a risk factor for developing ovarian cancer. So I
4 think that's part and parcel of the infertility risk
5 factor and not necessarily associated with an
6 inflammatory condition.

7 Q. Okay. And the last source of inflammation they
8 recognize that increases a woman's risk for ovarian
9 cancer is talc exposure is 2.3, the first sentence.

10 I'm on 430, Section 2.3, at the very beginning
11 of section -- it's page 4 of 30.

12 Of course you disagree with them on that as
13 well. Right?

14 A. Well, yes. And, also, what you were looking at
15 before, actually, really, got it wrong because I think
16 the last paragraph that you highlighted, it said that
17 talc could get to the ovaries from diaphragm use, and
18 we know from what we looked at earlier this morning,
19 having your diaphragm dusted with talc and using your
20 diaphragm decreases the odds ratio.

21 Q. Isn't it true the instructions that come with
22 the diaphragm tell you to rinse off the diaphragm
23 before you use it?

24 A. I don't know. I've never used a diaphragm.

25 Q. The next page, 5 of 30, Sections 2.4, you were

1 also asked some questions about this on direct
2 examination, and that's nonsteroidal anti-
3 inflammatory drugs, and what these authors say in the
4 first sentence is:

5 "Further connecting inflammation to EOC,
6 epithelial ovarian cancers, are several studies that
7 demonstrate that intake of nonsteroidal anti-
8 inflammatory drugs, NSAIDs, specifically of aspirin,
9 correlates inversely with risk of ovarian cancer and
10 endometrial cancer." And they cite four studies.

11 Do you agree there are studies that show
12 NSAIDs do reduce a woman's risk of ovarian cancer?

13 A. So what you've highlighted here agrees
14 completely with what I said this morning, but that
15 only further demonstrates the inconsistencies within
16 the NSAIDs, the literature, right, because using low
17 dose aspirin daily decreased the risk of a woman
18 getting cancer. But in some studies, using the
19 non-aspirin NSAIDs actually increased her risk of
20 getting cancer.

21 So if we're talking specifically about
22 aspirin, it does. But then when we expand the
23 conversation to the non-aspirin NSAIDs, which also are
24 anti-inflammatory drugs, the risk of ovarian cancer
25 has been shown to increase.

1 Q. At the time that you were formulating your
2 opinions about whether talc can cause ovarian cancer
3 and whether it would cause an inflammatory reaction in
4 cells, you had not considered five seminal cell
5 studies. You had not considered the Buz'Zard study.
6 Correct?

7 A. Are you asking about when I wrote my report?

8 Q. I've got your report and your deposition. And
9 according to your deposition, you hadn't considered
10 any of these five I'm about to read. Tell me if I'm
11 wrong.

12 A. I wouldn't say I hadn't considered. I hadn't
13 read them. That's true. But I knew of the studies
14 and knew what their findings were based on reading
15 plaintiffs' expert reports.

16 Q. So at the time of your formulation of your
17 causation opinions, and at the time of your deposition
18 even, you had not read the Buz'Zard 2007 study, right?

19 A. That's correct.

20 Q. And you had not read the Shukla 2009 study,
21 right?

22 A. That's correct.

23 Q. And you had not read the Fletcher Saed 2019
24 study, right?

25 A. So that's not exactly correct because I did not

1 read the published manuscript, but I had read
2 Dr. Saed's report for this matter which he himself
3 said in deposition testimony was the same thing as his
4 manuscript.

5 Q. Okay. And you hadn't read the Akhtar 2010 or
6 the 2014 studies?

7 A. Correct.

8 Q. And is it your testimony today, reading about
9 studies gives you enough information to testify on the
10 subject or the topic of these five studies beyond your
11 expertise?

12 A. I would not say the topic of these five studies
13 is beyond my expertise in terms of who I am as a
14 gynecologic oncologist. But the topic of those five
15 studies is not what I was retained to do in this
16 matter.

17 Other investigators, if you will, M.D.s,
18 Ph.D.s were being retained in this matter to weigh in
19 on if the cancer biology, and that was not my
20 understanding of what I was being asked to do in this
21 matter.

22 Q. Could you put up 515, please? These are the
23 five studies I'm referring to. I should have put this
24 up earlier so you could see it.

25 I think you said you did know about the

1 studies. You just chose not to read them because you
2 weren't asked to offer opinions on this topic. Am I
3 understanding that right?

4 A. I knew about the studies, and I knew from
5 reading the expert reports that none of these studies
6 actually showed malignant transformation.

7 So reading them I did not feel was important
8 to my opinion, and I knew that other people that
9 basically are cancer biologists were going to be asked
10 to evaluate the cancer biology questions in this
11 matter.

12 Q. With the exception of Dr. Saed, because you read
13 his report, someone told you about the results of
14 these studies and how you deemed they were unnecessary
15 for your opinions?

16 A. What I said was I read your expert reports, and
17 they described these studies in their reports, and I
18 knew from your experts' reports that none of these
19 studies demonstrated malignant transformation.

20 MR. DEARING: Can you put up slide 9.

21 Q. Some other things you did not consider in
22 forming your opinions, isn't it true you did not
23 consider whether talcum powder contains asbestos in
24 determining whether talcum powder use might contribute
25 to cause cancer?

1 A. That's true.

2 Q. And you did not consider whether fibrous talc is
3 contained in the powders and might contribute to cause
4 cancer. Right?

5 A. Might contribute to cause ovarian cancer.

6 Q. Ovarian cancer, right.

7 A. That's true.

8 Q. And you did not consider the carcinogenic heavy
9 metals in talcum powder in your analysis as to whether
10 it could cause ovarian cancer. Right?

11 A. If talc is the vehicle by which you are saying
12 all of these other things are getting to the women,
13 then that is true, I did not consider the components
14 within the talc. I focused on the baby powder itself,
15 the perineal application of the baby powder.

16 Q. If the baby powder contains asbestos and/or
17 fibrous talc and/or carcinogenic heavy metals and
18 potentially carcinogenic fragrance chemicals, and you
19 didn't consider those constituents, then you didn't
20 consider baby powder in its entirety, did you?

21 A. Yes, I did because I focused on the literature
22 that examined the perineal application of talc and
23 whether or not the risk of ovarian cancer is
24 increased. If talc contains all of these elements
25 that you are purporting are in there, and that would

1 make the talc carcinogenic, there would be an
2 increased risk of developing ovarian cancer with the
3 perineal application, and that is not supported by the
4 literature.

5 Q. If asbestos was in talc, and if it migrated to
6 the ovaries, do you believe that it would cause an
7 inflammatory reaction there?

8 A. Are we talking pure hypothetical?

9 Q. Yes.

10 A. Asbestos is a Group 1 carcinogen by IARC. I do
11 not believe there is a risk, an increased risk with
12 baby powder, the way that it is now, the way that it
13 has been used since, it's been studied since 1982.

14 So I assume asbestos could cause an
15 inflammatory response someplace, but it's not
16 something I've studied.

17 Q. Do you have an opinion about whether asbestos
18 can cause ovarian cancer?

19 A. So I know that IARC has published and stated
20 that there is an increased risk of ovarian cancer in
21 woman that have had heavy occupational exposure to
22 asbestos, but I think there are problems with those
23 studies. But that is what IARC said.

24 Q. And I'm asking Dr. Saenz's opinion, do you have
25 an opinion on whether asbestos can cause ovarian

1 cancer?

2 A. It's unfortunately not a yes or no answer for me
3 because I think that I acknowledge what IARC has
4 published, but I think there are some problems with
5 the studies that have been done, and not all the
6 studies have shown an increased risk of developing
7 ovarian cancer with heavy occupational exposure to
8 asbestos. So I don't think it's as clear an issue as
9 IARC has stated.

10 Q. That's exactly why we talk in terms of biologic
11 plausibility. So let me ask you this question:

12 In your opinion, is it biologically plausible
13 if talc contains asbestos and fibrous talc, or
14 carcinogenic heavy metals, or carcinogenic fragrances,
15 and it does reach the ovaries, isn't it biologically
16 plausible that could cause an inflammatory reaction
17 that may set in motion a cascade of a reaction that
18 turns into cancer?

19 MR. WILLIAMS: Objection, your Honor. That's
20 clearly not something Dr. Saenz has been asked to
21 opine on in the matter. She already testified as to
22 the limitations on her knowledge in that area. We
23 don't think it's appropriate for counsel to ask her, a
24 person who has indicated she is not an expert in
25 asbestos to provide that opinion.

1 MR. DEARING: I believe that was asked on
2 direct about biologic plausibility of talc, and if
3 she's going to talk about talc, we have to talk about
4 the constituents that are in talc.

5 THE COURT: I'll let the Doctor answer
6 herself. I think she said she did not consider
7 components. She's not an expert in heavy metals and
8 asbestos. She considered talc as a whole, whatever
9 may be in it.

10 I think that was your answer this morning?

11 THE WITNESS: Yes, your Honor.

12 THE COURT: That has been her testimony
13 throughout, regardless of what she's looking at as a
14 whole, but we can ask her that question and have her
15 clarify at this time.

16 MR. DEARING: Let me ask the inverse of the
17 question.

18 Q. Is it your opinion it's not biologically
19 plausibility that talc can cause ovarian cancer, and
20 is that opinion without regard to whether the talc
21 contains asbestos, fibrous talc, carcinogenic heavy
22 metals, or fragrances?

23 A. That's correct.

24 Q. You don't know whether if talc did contain those
25 things, that would change your opinion because you are

1 not an expert in that field?

2 A. It would not change my opinion because the
3 literature I looked at, talc literature, so if there
4 were components within the talc that are getting to
5 the woman via the talc, the talc literature would show
6 an increased risk of ovarian cancer, and it does not.

7 So my opinion is regardless of the
8 constituents that are in the talc, regardless,
9 perineal application of talcum powder does not
10 increase the risk, nor does it cause ovarian cancer.

11 Q. Did I just hear you say there is no literature
12 to suggest that perineal talc use increases a woman's
13 risk of ovarian cancer?

14 A. The sum of the literature, the sum of everything
15 we have been discussing here, looking at the sum of
16 the case-control studies, looking at the cohort
17 studies, the inconsistencies within the case-control
18 studies, between the case-control studies and the
19 cohort studies, the inconsistencies within the
20 individual case-control studies, all of that, all of
21 that is what I've examined as well as the literature
22 on inflammation, the literature on NSAIDs, the slides
23 on patients that have surgery, that have precursor
24 lesions for ovarian cancer that do not show
25 inflammation, all of that is what I have used to form

1 my opinion.

2 Q. With regard to those slides, isn't it true that
3 if you are looking at a slide of tumor tissue, you
4 will not expect to see the precursor lesion that
5 initiated that cancer process because it's obliterated
6 by the tumor?

7 A. I'm not talking about the slides where the
8 cancer already developed. I'm talking about the
9 slides that are on the women who have had prophylactic
10 surgery, and we can identify the STIC lesions and the
11 p53 signatures which are the precursors to the high
12 grade serous carcinomas. There is no inflammation
13 there.

14 So if those cancers are in the process of
15 developing and you are proposing that chronic
16 inflammation is the inciting event, that should be
17 there, where the precancer is, and it's not.

18 Q. Are you screening the women that you are
19 prophylactically giving oophorectomies to, whether
20 they are talc users? Are you asking them that
21 question?

22 A. No, but your hypothesis is that even exclusive
23 of talc, that chronic inflammation is causing ovarian
24 cancer. And what I'm saying is talc or not, chronic
25 inflammation is not causing the high grade serous

1 carcinoma. The biology doesn't bare that out.

2 Q. But you can tell postmenopausal, by looking at
3 pathology slides of an ovarian cancer tumor?

4 A. That's not what I'm saying. What I'm saying is
5 I'm looking at the precursor lesions, and there is no
6 inflammation.

7 Q. I guess my problem is, if you remember looking
8 at what you are calling precursor lesions, but you can
9 never take the tumor and trace it back to those
10 precursor lesions, because the precursor lesion here
11 gets destroyed and subsumed in the tumor. So you are
12 speculating whether those precursor lesions will morph
13 into a cancer. Right?

14 A. Not entirely true and not supported by the
15 science.

16 So one of the criteria for diagnosing
17 fallopian tube cancer as opposed to cancer that
18 originated in the ovary is that somewhere in that
19 fallopian tube, as you examine the entire fallopian
20 tube, you need to find that STIC lesion. That's how
21 the pathologists said this came from the fallopian
22 tube as opposed to the ovary.

23 So not entirely true. It's a precursor lesion
24 that allows you to call out and say this is fallopian
25 tube carcinoma. So you might have a big old tumor but

1946

1 you also have to have evidence of the spectrum, if you
2 will, of development.

3 Q. You talked some about the Society of Gynecologic
4 Oncology, the SGO. You are a member of SGO. Right?

5 A. Yes.

6 Q. You are a member of ACOG. Right?

7 A. I'm a fellow, yes.

8 Q. You are a member of the American Congress of
9 Obstetrics and Gynecology?

10 A. Yes.

11 Q. Are you Board Certified in OBGYN?

12 A. Yes.

13 Q. Are you Board Certified in gynecologic oncology?

14 A. Yes.

15 Q. When did you become Board Certified in
16 gynecologic oncology?

17 A. 2001.

18 Q. How do you become Board Certified in gynecologic
19 oncology?

20 A. Well, you have to complete a fellowship
21 successfully, and then at the completion of your
22 fellowship, you take a written exam, and then you --
23 it's different now than when I did it. You don't have
24 to -- I think for me, when I did it, I had to wait
25 1 1/2 to two years before I could collect cases to sit

1 for my oral examinations.

2 Q. Once you become Board Certified, what do you
3 have to do to maintain it? Do you have continuing
4 education requirements?

5 A. We do.

6 Q. Is that the only thing you have to do to
7 maintain it?

8 A. I think you have to maintain hospital privileges
9 in good standing and submit to the Board that you have
10 that, and your maintenance of Certification means that
11 you have to read 30 articles a year that are posted
12 online, answer test questions about those articles,
13 and receive a passing score, and you have to every
14 year do at least two different chart pulls, if you
15 will, to make sure your practice is consistent with
16 certain objectives of the field.

17 Q. Who makes up the American Board of Obstetrics
18 and Gynecology? Is it other gynecologic oncologists
19 around the country?

20 A. No, it's general OBGYNs, maternal, fetal,
21 medicine specialists, some gyne-oncologists --

22 Q. Is there a subspecialty you can be Board
23 Certified in, and that's gynecologic oncology?

24 A. Yes.

25 Q. Is it the same Board that oversees both the

1 General American Board of Obstetrics and Gynecology
2 and the Gynecologic Oncology Board Certified?

3 A. Yes.

4 Q. Have you ever served on the American Board of
5 Obstetrics and Gynecology?

6 A. No.

7 Q. Have you ever served on any of their committees?

8 A. Not on the Board's committees, no.

9 Q. Do you know Dr. Steve Plaxe at UC San Diego
10 School of Medicine? I only ask because I noticed he
11 sits on the GYN Oncology Committee. Do you know him?

12 A. He is one of my partners.

13 Q. So being Board Certified in Gynecologic Oncology
14 sort of sets you apart from, I guess, other non-Board
15 Certified physicians as having demonstrated a certain
16 expertise in that area. Would you agree?

17 A. Well, it means I have specialty training. But
18 many people have specialty training. They are just
19 boarded in their specialties. What you said sounds a
20 bit elitest, and I'm trying not to sound elitest.

21 Q. Do you know whether the American Board of
22 Obstetrics and Gynecologists recognizes talc as a
23 contaminant that might cause cancer?

24 A. I don't believe the Board considers it a risk
25 factor per se in the situation by which posting risk

1 factors because that's not the responsibility of the
2 Board. I do know that the Board has this list of
3 learning objectives per se that it puts forth for
4 fellowship candidates to learn, and one of the
5 subjects it talks about is talking about potential
6 risk factors that are out there being discussed, and
7 one of the learning objectives in terms of talking
8 about environmental exposures, the Board does list
9 talc as one of them.

10 Q. Let's look at Plaintiffs' Exhibit 13, slide 3.
11 This is the guide to learning in gynecologic oncology.
12 This gives you sort of an outline of the things you
13 are expected to know about for the exam and be board
14 certified. Right?

15 A. It's kind of a listing of topics that the fellow
16 should be prepared to discuss in their oral
17 examination. Can you go to the next page, please.
18 That explains more in detail what it is.

19 Then if you would go to page 13, please. If
20 you look at Roman numeral III, 8, subsection B 1(e).

21 Q. It says:

22 "The fellow should understand and be able to
23 describe" and it lists all these things, and one is
24 "environmental contaminants such as the relationship
25 of talc and asbestos to ovarian and other malignancies

1950

1 and smoking to lower genital track cancer."

2 Do you agree this is one of the topics the
3 American Board of Obstetrics and Gynecologists
4 specifically requires their physicians to know things
5 about in order to become Board Certified?

6 A. So this listing is a list of topics that the
7 fellowship candidate should be prepared to discuss and
8 review the literature in order to be a responsible
9 gyne-oncologist, yes.

10 Q. The topic suggests that "environmental
11 contaminants such as the relationship of talc and
12 asbestos to ovarian cancer and other malignancies" --
13 there is an implication in that statement those things
14 are not theoretical, that there is an established
15 relationship, and that's what it says. Right?

16 MR. WILLIAMS: That misstates the document,
17 your Honor.

18 THE COURT: Let me have her answer the
19 question, please, as to what she thinks that's saying.

20 A. I think that's your interpretation, because, in
21 fact, what the Board wants is fellows and fellowship
22 candidates to be responsible by doing a comprehensive
23 review of the literature to come to appropriate
24 conclusions. So, for example, right above the segment
25 that you've highlighted they talk about viruses

1 including herpes. This is for GYN oncology. Herpes
2 is not associated with the development of gynecologic
3 malignancies. It used to be thought cervical cancer
4 was caused by herpes, but now we know that's not true.
5 So in the same vein, I think the Board is putting out
6 there talc and discussed its relationship to ovarian
7 and other malignancies because fellowship candidates
8 should be prepared to have that discussion.

9 Q. HPV virus, that's not a theoretical cause of
10 cervical cancer, is it?

11 A. No, but herpes is, and that's still listed
12 because the Board wants the fellows to be able to have
13 a discussion where they can say, we once thought this
14 was the case for cervical cancer, but now we know it's
15 not true. Likewise, the board would want educated
16 fellows to be able to have a discussion about the
17 relationship between talc and the development of
18 ovarian cancer. They want their fellows to stay
19 current.

20 Q. And just beneath that it says:

21 "Genetic mutations"-- and genetic mutations
22 are not a theoretical cause of ovarian cancer, are
23 they?

24 A. No, they are not.

25 Q. Where it says:

1 "Environmental contaminants such as the
2 relationship of talc and asbestos," it doesn't say
3 such as the theoretical relationship of talc and
4 asbestos, does it?

5 A. It doesn't say that with the herpes either, but
6 that is the case.

7 Q. It says that fellows should be prepared to have
8 a discussion about talc and ovarian cancer. Yet
9 you've told us you don't have that discussion with
10 your patients. Right?

11 A. This is to be prepared for the board exam, sir.
12 That's not the intent of this document.

13 Q. What's the purpose of learning about the
14 relationship of talc and ovarian cancer if you are not
15 going to share it with your patients?

16 A. If you get asked a question you can answer it in
17 an educated format which I have said I do with my
18 patients if asked.

19 MR. DEARING: That's all I have, your Honor.
20 Thank you.

21 THE COURT: Let's take a break.

22 THE DEPUTY CLERK: All rise.

23 (Recess.)
24
25

1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4 **CHERYL C. SAENZ**, resumed.

5

6 REDIRECT EXAMINATION

7 BY MR. WILLIAMS:

8 Q. Dr. Saenz, I just have a few clarifying
9 questions if I could.

10 The first topic is the Savant study from 2018.
11 It's an MDL Exhibit P-527. Plaintiffs' counsel showed
12 you that article. Do you recall that?

13 A. Yes, I do.

14 Q. And you mentioned that it was a review article.
15 Is that right?

16 A. That's correct.

17 Q. And what was the significance of your saying
18 this is a review article?

19 A. Well, review articles are not peer-reviewed in
20 the same sense as a primary study might be. So they
21 are reading a bunch of different articles and putting
22 together a summary. A review article is not bringing
23 anything additional to the science itself because it's
24 just summarizing what's already been published.

25 Q. Let me direct your attention to the portion of

1 the article that related to talc in particular. It's
2 on page 5. There's a paragraph that begins with the
3 word "talc." Do you see that?

4 A. Yes.

5 Q. What it says is:

6 "Talc is a silicate mineral, and exposure to
7 it can cause inflammation of the ovaries and poses a
8 risk hazard for development of EOC."

9 And there is a citation. Do you see that?

10 A. Yes.

11 Q. That citation No. 45, if we go to page 20 of
12 Exhibit P-527, is to the Heller study. Is that right?

13 A. That's correct.

14 Q. That's the same Heller study we talked about a
15 lot. Right?

16 A. That's correct.

17 Q. Does the Heller study provide evidence that talc
18 causes ovarian cancer?

19 A. No, it does not.

20 Q. How about the second portion -- the first
21 portion of the sentence that talc causes inflammation
22 of the ovaries. Did the Heller study say anything
23 about that?

24 A. No. In fact, the Heller study is that study you
25 recall that looked at 24 women, 12 of whom reported

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1 perineal application of talc, 12 of whom denied they
2 had applied talc to their genitalia and found talc in
3 the ovaries of all 24 women. Heller then went on to
4 examine microscopically one of the ovaries for
5 evidence of inflammation and found none.

6 Q. There was some discussion about diapering with
7 respect to the Heller study. Do you remember that?

8 A. Yes.

9 MR. WILLIAMS: If we can pull up A 60, the
10 Heller study, page 4 of 5, Table II, A 60 page 4,
11 Table II.

12 Q. First a preliminary question: Do you happen to
13 know, Doctor, the latency period for ovarian cancer --
14 20, 30, 40 years? Do you happen to know what the
15 literature says on that latency necessarily means to
16 talk about whatever particular exposure you are
17 talking about?

18 A. We don't really know what the latency is for any
19 environmental exposure, and ovarian cancer, other than
20 there is some suggestion from the asbestos literature
21 that the latency for asbestos and the risk of ovarian
22 cancer is somewhere around 20 to 25 years.

23 Q. If we look at this chart, if it were 20 to
24 25 years, and we look at the ages of the women
25 involved in the study, that would suggest that they

1956

1 were being diapered well after their infancy. Would
2 that be accurate to say assuming a 20- to 30-year
3 latency?

4 Let me back up. This is the Heller study and
5 Table II listed the ages of the women who were
6 studied. It said they had talc in their ovaries, some
7 of them did and some of them didn't. Do you recall
8 that?

9 A. Yes.

10 Q. Counsel on cross-examination suggested, isn't it
11 true there are six of the women who said they
12 remembered they were diapered in their infancy? Do
13 you recall that cross-examination?

14 A. I recall that he said that. I don't remember
15 that fact, but that's okay.

16 Q. Assume for purposes of the question that the
17 study says that there were six women who said they
18 were diapered in their infancy. If the latency period
19 as you just described for asbestos that you've heard
20 is 20 years --

21 THE COURT: You mean being diapered with baby
22 powder.

23 MR. WILLIAMS: Yes, being diapered with baby
24 powder.

25 THE COURT: They're all diapered I'm sure.

1 MR. WILLIAMS: Thank you, your Honor.

2 BY MR. WILLIAMS:

3 Q. If the women were the ages that are listed in
4 Table No. 2 and the latency period, were as you
5 described, that would mean they would have been
6 diapered well after their infancy. Is that accurate?

7 A. You can say that or you can flip this and say
8 many of these women, if they were diapered with baby
9 powder, they are now of the age that at least 25 years
10 have passed and we would expect to see in their
11 ovaries either inflammation or ovarian cancer, if,
12 indeed, that is the mechanism by which talc is
13 inducing ovarian cancer.

14 Q. And what we do know about the Heller study is
15 that half of the women reported that they had never
16 used talc in the perineal area, but there was talc in
17 their ovaries nevertheless. Correct?

18 A. That's correct.

19 Q. You were asked questions about the IARC
20 monograph, and, specifically, it's Exhibit A 58. You
21 read the monograph. Correct?

22 A. Which one are we talking about?

23 Q. You were asked questions about the Health Canada
24 draft assessment. That's what I'm talking about now.
25 Did you read that?

1 A. Yes.

2 Q. It's Exhibit A 58. Let me call up page 12, if I
3 could. Do you recall reading this portion, the third
4 paragraph, second full paragraph, that speaks about
5 all of the various exposures that we have to talc.

6 A. Yes.

7 Q. It references here chewing gum, dried legumes,
8 rice, all the ways that we are exposed to talc in our
9 lives. Do you remember that?

10 A. Yes.

11 Q. In the next paragraph it says that talc is
12 present in approximately 8500 self-care products?

13 Do you see that?

14 A. Yes.

15 Q. Do you have an understanding as to whether talc,
16 based upon your reading, talc is contained in vitamins
17 or supplement pills that we take?

18 A. Talc is in almost every pill that we take,
19 actually every prescribed medication. It's a
20 component of all of those medications.

21 Q. What I'm getting at is, is there any basis for
22 believing that the existence of talc in the body is
23 necessarily associated with a woman's perineal use of
24 talcum powder as opposed to the other manners in which
25 we are all exposed to talc?

1 A. Right. There is no data, as we discussed really
2 throughout most of the day today, that talc applied to
3 the genital region makes it to the ovaries, and there
4 are many other applications of talc that we put into
5 our bodies on a daily basis.

6 Q. One of the exhibits that you were shown was the
7 Langseth 2007 exhibit.

8 MR. WILLIAMS: For the record, your Honor, it
9 was PSC Opposition Exhibit 5.

10 Q. Counsel showed it to you on the topic of
11 migration. Do you recall that?

12 A. Yes.

13 Q. Let me direct you to the conclusion of the
14 study. I'll just use the ELMO for this. This is PSC
15 Opposition Exhibit 5, page 359.

16 A. Counsel, if I may, I believe that based on
17 reading the abstract before, I told Mr. Dearing that I
18 had no recollection, I couldn't recall as I sat here
19 whether or not I had seen this paper before. And as I
20 look at this table, it refreshes my memory. I have
21 seen this paper before. I just want to clean up the
22 record for that.

23 Q. I just wanted to direct your attention to the
24 end of the paper that talks about it as a proposal to
25 the research community. Is this the Langseth study

1 that you read that concluded here:

2 "The current body of experimental and
3 epidemiological evidence is insufficient to establish
4 a causal association between perineal use of talc and
5 ovarian cancer risk."

6 A. Yes.

7 Q. Counsel showed you a Daniel Cramer study from I
8 believe 2007. It's one you will recall he co-authored
9 with Dr. Godleski from Harvard. Do you remember that
10 line of questioning?

11 A. Yes.

12 Q. For the record, it's Exhibit P-SC Opposition
13 Exhibit 76. Here is the cover page, Dr. Saenz.

14 I want to direct your attention to a statement
15 contained on page 500 here. Do you see over in the
16 right-hand column the authors wrote:

17 "Also we are not claiming that a causal
18 relationship between ovarian cancer and talc use is
19 proven for this case or in general."

20 Is that part of the same study that was put in
21 front of you?

22 A. Yes, it is.

23 Q. Counsel put in front of you Blaustein's
24 "Pathology of the Female Genital Tract." That was PSC
25 Saenz 14.

1 I want to direct your attention to this page
2 which counsel showed you under the heading
3 "Inflammation." Counsel read the first few sentences
4 here down to the word "carcinogenesis." You drew
5 counsel's attention to the very first line that said
6 "It has been suggested," and you pointed out that
7 word. Do you remember that?

8 A. Yes, I do.

9 Q. I want to direct your attention to the sixth
10 line, the sentence that begins "Evidence of pro-
11 inflammatory microenvironment in endometriosis
12 supports this hypothesis for Type I tumors."

13 Does the use of the word "hypothesis" make the
14 point that you were making about this section on
15 inflammation?

16 A. It does. I think what I stated was something
17 very much along the lines of a suggestion is a
18 hypothesis.

19 Q. And then below, under "Other Risk Factors,"
20 counsel read this portion that said:

21 "Other potential risk factors have been
22 studied but associations with ovarian cancer risk are
23 weak or inconclusive," and then it goes on to list a
24 number of things.

25 My question to you is, is that consistent with

1962

1 your reading of the literature with respect to talc in
2 particular, that is, that any sort of an association
3 is indeed weak and inconclusive with respect to
4 causation?

5 A. I would take it further, counsel. I believe the
6 odds ratio from the case control literature has shown
7 a weak association in the range of 1.2 to 1.4. But I
8 don't consider the literature inconclusive. I believe
9 that it is conclusive right now in terms of the state
10 of the science, and this is in part due to the fact
11 that the cohort studies do not show an association.
12 The case-control studies are inconsistent within and
13 of themselves. There is no biologically plausible
14 mechanism by which the talc would be inducing chronic
15 inflammation.

16 Q. You were asked some questions about the U.C. San
17 Diego website. Do you recall that?

18 A. About the U.C. San Diego website that they put
19 up the questionnaire?

20 Q. That's right.

21 A. Yes.

22 Q. In the questionnaire that was put up counsel
23 directed your attention to the name of a Dr. Richard
24 J. LoCicero. Do you remember when that was placed up
25 there?

1 A. He is not UCSD faculty.

2 Q. You know that because you know the UCSD faculty
3 tree. Is that true?

4 A. That's true.

5 Q. Now, we looked over the break for Dr. LoCicero,
6 Richard J. LoCicero. This indicates that he is from
7 the Vanderbilt University. That's where he got his
8 medical degree, and that he is affiliated, that he's
9 an oncologist and hematologist. Do you see that?

10 A. Yes.

11 Q. Under hospital privileges down at the bottom, it
12 references that he works out of Georgia. Right?

13 A. Right. So someone like him would be contacted
14 by, say, a third-party vendor to write a document such
15 as that, which has been posted on the UCSD website.
16 He's essentially contracted to write those things.
17 It's not reflective of what the UCSD faculty believes.

18 Q. Let me ask you some questions about the website,
19 not the questionnaire portion, but the website that
20 lists risk factors itself, if I could.

21 MR. WILLIAMS: If we can bring up exhibit
22 Saenz 505?

23 Q. This document is not a quiz, is it? This is
24 just a listing of risk factors?

25 A. Correct.

1 Q. And it describes "a risk factor is anything that
2 may increase your chance of having a disease. Risk
3 factors for certain types of cancer might include
4 smoking, diet, family history, or many other things,"
5 and it lists things you should know about the risk for
6 cancer. And there are three bullet points. See that?

7 A. Yes.

8 Q. None of those reference talc. Is that right?

9 A. That's correct.

10 Q. Down below there is a separate paragraph that
11 says:

12 "Some risk factors, such as family history,
13 may not be in your control, but other things you can
14 change. Knowing the risk factors can help you to make
15 choices that might lower your risk. For example, if
16 an unhealthy diet is a risk factor, you may chose to
17 eat healthy food," and it references weight and so on.
18 Correct?

19 A. Yes.

20 Q. Under this portion of the website that lists
21 risk factors for ovarian cancer, is talc listed?

22 A. No.

23 Q. Let me end by talking about the Berge case.
24 Counsel asked you some questions.

25 For the record, it's Exhibit A 11.

1965

1 I would like to direct your attention to page
2 9 of Berge and ask you this:

3 You have described how -- and counsel has put
4 in front of you the forest plot where the point
5 estimates are to the right of 1. Do you recall that?

6 A. Were we looking at Penninkilampi for that, I
7 thought?

8 Q. Yes, we were. I'm not suggesting Berge did it.
9 If we could go to the ELMO very quickly. This is the
10 forest plot I believe that counsel placed in front of
11 you on cross-examination. Do you recall that?

12 A. Yes.

13 Q. And he pointed to the odds ratios being to the
14 right of 1. You remember that, right?

15 A. Right.

16 Q. My question going back to Berge, do you remember
17 that Berge -- and this is page 9 of Exhibit A 11, left
18 column.

19 Do you recall that that study talks about the
20 notion of the predominance of the retrospective
21 case-control studies as it relates to a meta-analysis?

22 A. Yes.

23 Q. And you see the sentence here, it says:

24 "Also, there were limitations not specific to
25 our study, including" -- and then there is a list of a

1 few things, "the predominance of retrospective
2 case-control studies."

3 Do you see that?

4 A. Yes.

5 Q. What do understand that to mean?

6 A. What that discussion is pertaining to is that
7 there were many more women in the case-control studies
8 than there were in the cohort studies. The volume of
9 cases was in the case-control studies. The authors
10 are also acknowledging that there was no external
11 validation data, meaning that these women
12 self-reported their main exposure of interest. They
13 weren't interviews per se. They were women simply
14 answering retrospectively about their talc use, and,
15 essentially, the authors are basically discussing the
16 biases that are inherent to the case-control studies.

17 Q. Just the sheer numbers, right. If there are 20
18 something case-control studies, then there are only a
19 few of the cohort studies. Does that have an impact
20 on this notion of predominance?

21 A. It does. It's dependent on not just the number
22 of studies per se, although that influences it, but
23 the women that were in -- the numbers of women in each
24 of those studies as well, and the predominance favored
25 the case-control studies.

1 Q. Now, let's end with the last page of this
2 exhibit. It's actually page 10, just before the
3 acknowledgements.

4 In the Berge study, after going through its
5 analysis of which study to include and which not, the
6 analysis of the cohort studies as well as the
7 case-control study concluded:

8 "Several aspects of our results, including the
9 heterogeneity of results between case control and
10 cohort studies, however, do not support a causal
11 interpretation of the association."

12 Did I read that right?

13 A. Yes.

14 Q. Based upon your review of the studies, the data,
15 the information from the cancer watchdogs, if you
16 will, and the organizations that you have reviewed,
17 and based upon your experience for the last 25 years,
18 is there a way reasonably to read that data as
19 suggesting that there is a causal association between
20 talc use and ovarian cancer that is consistent, that
21 is strong, as opposed to weak and inconclusive and
22 lacking in biological plausibility?

23 A. No, there is not, and the authors of Berge
24 concur.

25 MR. WILLIAMS: No further questions, your

1 Honor.

2 THE COURT: Thank you.

3

4 RECROSS-EXAMINATION

5 BY MR. DEARING:

6 Q. Does your institution know or disclose on its
7 website that the content is not reviewed for accuracy
8 by staff physicians?

9 A. I don't know.

10 Q. Does your institution disclose on its website
11 that the content may not be accurate?

12 A. I don't know.

13 Q. Does your institution disclose on its website
14 that the content is meant for marketing and not for a
15 woman's health?

16 A. I don't know.

17 Q. Were you aware your institution's website
18 mentions talc as a possible risk factor for ovarian
19 cancer before we had that conversation?

20 A. Before I had what conversation?

21 Q. Today with me when I asked you about your
22 website.

23 A. No.

24 Q. Mr. Williams mentioned the Savant article. I
25 think he suggested that there is no suggestion here

1969

1 that talc causes inflammation and increases the risk
2 of ovarian cancer, and I wanted to direct you back to
3 it. So would you turn to 115. Let's look at page 6.

4 This is the inflammation model in Savant, and
5 it identifies sources of inflammation in the ovary and
6 fimbriae, and it talks about talc exposure right
7 there. Right?

8 So would you agree this article does discuss
9 and proposes that talc exposure to the ovary does
10 create an inflammatory reaction which could be a
11 precursor to cancer?

12 A. This is a cartoon graphic, if you will, again,
13 for the hypothesis that talc exposure causes chronic
14 inflammation. But this is still just their
15 suggestions/hypothesis. This is not proof. This is
16 not documentation of a mechanism.

17 Q. Since your working in California, are you
18 familiar with the California Department of Public
19 Health Occupational Health Cosmetic -- California Safe
20 Cosmetics Program?

21 MR. WILLIAMS: Beyond the scope, your Honor.

22 THE COURT: Sustained.

23 BY MR. DEARING:

24 Q. Do you know whether the state of California
25 recognizes talc as a carcinogen?

1 MR. WILLIAMS: Same objection.

2 THE COURT: Sustained.

3 BY MR. DEARING:

4 Q. You mentioned that there was no current or
5 recent regression model that suggested that talc was a
6 risk factor, and I wanted to draw your attention to
7 the Wu study, which is a 2015.

8 A. I believe you are misstating my testimony. What
9 I said is that there is no algorithm -- I think at the
10 time we were looking at that paper from Lake Como, and
11 what I said is there is no algorithm in clinical
12 practice that you plug in risk factors to assess a
13 woman's risk of ovarian cancer. There is nothing like
14 that in clinical practice.

15 Q. Okay.

16 A. I didn't say other authors haven't published. I
17 said nothing in clinical practice.

18 Q. I thought you said there was nothing recent.

19 A. I said there is nothing in clinical practice in
20 2019 that algorithm was suggested in 2007.

21 Q. This says:

22 "We used multivariate logistic regression to
23 examine parity, oral contraceptive use, tubal
24 ligation, endometriosis, family history of ovarian
25 cancer, and talc use, and risk of invasive epithelial

1971

1 ovarian cancer among Hispanics, African-Americans, and
2 non-Hispanics Whites."

3 So that is exactly what the Wu scientists did;
4 they created a multivariate logistic regression to
5 look at those risk factors?

6 A. You are completely misrepresenting what this is.

7 Q. I am?

8 A. You are.

9 Q. We can read what it is.

10 A. This is not an algorithm to calculate a woman's
11 odds ratio. The authors of this study sat down. The
12 intent of their study was to look at the following
13 risk factors: parity, oral contraceptive use, tubal
14 ligation, endometriosis, et cetera, and calculate odd
15 ratios for the risk of developing ovarian cancer.
16 This is not an algorithm that is to be applied in
17 clinical practice. You can poll every case-control
18 study. You will see something in the methods section
19 that talks about multivariate logistic regression that
20 is the statistical technique to evaluate the influence
21 or the odds ratio of each and every one of these risk
22 factors on the development of ovarian cancer.

23 Q. I don't think you heard my question.

24 THE COURT: I don't think there was even a
25 question, so let's go back, Doctor, and listen to his

1 question. He did not have one yet. All he had done
2 was read what was in this study. So let's go back,
3 please.

4 BY MR. DEARING:

5 Q. Isn't it true they used talc use as a risk
6 factor to calculate the risk of invasive epithelial
7 ovarian cancer? They list it right there?

8 A. They evaluated the use of talc and the risk of
9 ovarian cancer, correct.

10 Q. You mentioned the Heller study on redirect. I
11 just wanted to ask you something.

12 You remember in the Heller study one of the
13 calculations they discovered when they were
14 calculating the particle burden in the tissue was that
15 the women who reported talc use actually reported
16 about three times more -- actually was found to have
17 about three times the particle burden of the women who
18 did not use talc. Do you see that?

19 A. In five of the subjects, yes -- I'm sorry.
20 Could you put that back up for a second?

21 Q. Yes.

22 (Pause.)

23 A. Yes.

24 Q. The five that reported talc use, five of the 12,
25 they had almost three times the number of talc

1973

1 particles as those with no reported talc use. Right?

2 A. Right. It was about 2.5 times, but, yes.

3 Q. Real quickly, can you pull up PSC 76, please.

4 One more quick look at this Cramer study. This is the
5 study Mr. Williams just mentioned, Cramer 2007.

6 He took you to the quote that says,
7 "Essentially, this study doesn't establish that talc
8 causes ovarian cancer." Do you remember that quote?
9 I can find it exactly.

10 A. Correct.

11 Q. But you know this is a case note involving a
12 68-year-old woman. Right?

13 A. Okay.

14 Q. No reasonable scientist is ever going to suggest
15 causation based on what they find in a single patient,
16 are they?

17 A. No.

18 Q. And that was not the intent of the study?

19 A. I don't know the intent of the study other than
20 it was to describe what their findings were.

21 Q. They were not trying to establish causation in
22 that study, were they?

23 A. No. That's what they said in their discussion
24 section, they weren't trying to establish causation.

25 Q. Because you cannot do that with one patient.

1 Right?

2 A. No responsible scientist would try to establish
3 causation with one patient. That is correct.

4 Q. Isn't it true you did not complete a full
5 Bradford Hill analysis when you were forming your
6 causation opinions in this case?

7 A. So I did not complete a Bradford Hill analysis
8 under the guise of describing it as a Bradford Hill
9 analysis, but in my review of the literature and in
10 the writing of my report I actually did look at many
11 of the criteria.

12 In fact, I would say almost all of the
13 criteria that are described in a Bradford Hill
14 analysis. I looked for strength of association. I
15 looked for consistency. I look for coherence. I
16 looked for what I call dose-response, which I believe
17 Bradford Hill refers to as biologic gradient.

18 I weighed all of the literature, the things
19 that I reviewed very much along the lines of a
20 Bradford Hill analysis.

21 Q. You would agree the Bradford Hill is
22 generally-accepted as a method by which causation can
23 be determined, right, or at least a causal
24 association?

25 A. Yes.

1975

1 Q. To do a complete Bradford Hill analysis you have
2 to consider the totality of the evidence. Right? The
3 totality of the studies, whatever you are researching?

4 A. Yes.

5 Q. Since you heard some of the testimony yesterday,
6 do you agree that qualified, skilled scientists can
7 conduct a Bradford Hill analysis and actually reach
8 different conclusions at the end?

9 A. No, I don't agree with that because I think the
10 methodology of the folks that have come to this room
11 and testified that talc causes ovarian cancer, I think
12 their methodology was flawed in the way that they
13 conducted their analysis, because the only conclusion
14 that you can draw is that talc does not cause ovarian
15 cancer.

16 Q. If you do a thorough review, Doctor, you just
17 said that a thorough complete Bradford Hill analysis
18 requires consideration of the totality of the
19 evidence.

20 Isn't it true that when you were formulating
21 your opinion, you didn't consider the in vitro studies
22 pertaining to talc?

23 A. That's not entirely true because I actually read
24 Dr. Saed's experiments, and I also knew from your
25 expert reports -- for example, the Shukla study and

1976

1 Buz'Zard study did not show any evidence of malignant
2 transformation. So I considered them in my analysis.

3 Additionally, one of the Bradford Hill
4 criteria, which is experimental evidence, Bradford
5 Hill in the actual document that is the Bradford Hill
6 criteria, says that evidence of experimental evidence
7 is not essential for a proper conduction of a Bradford
8 Hill analysis.

9 Q. But you didn't read the cell studies, the Shukla
10 studies, the Buz'Zard studies, the Saed studies?

11 A. I did read the Saed studies, that's incorrect.

12 Q. I believe you read the report of Dr. Saed. You
13 didn't read his studies. Right?

14 A. That is his study. His report is his study. He
15 testified to that in his deposition.

16 Q. You didn't read the other four studies.
17 Correct?

18 A. The other four studies we talked about earlier?

19 Q. Yes.

20 A. I did not read those prior to writing my report
21 but I did know what the content of them was, and it
22 was not important to my analysis.

23 Q. One last question for you, Doctor: Based on the
24 IARC assessment of asbestos and risk of ovarian
25 cancer, I want you now to assume that there is

1977

1 asbestos in Johnson & Johnson's talcum powder
2 products. Is it your testimony that you would counsel
3 your patients that it is safe, based on your review of
4 the literature, to put that product containing
5 asbestos on her genitals? Is that your testimony?

6 A. Yes.

7 MR. DEARING: Thank you. That's all I have.

8 MR. WILLIAMS: No questions, your Honor.

9 THE COURT: You are excused.

10 (Witness excused.)

11 THE COURT: Off the record.

12 (Discussion off the record.

13 THE DEPUTY CLERK: All rise.

14 (Court concluded at 4:00 p.m.)

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I N D E X

Proceedings

Page

WITNESSES

Direct Cross

Redirect

Recross

Cheryl C. Saenz

By Mr. Williams

1798

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1953

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By Mr. Dearing

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1863

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1969

C E R T I F I C A T E

PURSUANT TO TITLE 28, U.S.C., SECTION 753, THE
FOLLOWING TRANSCRIPT IS CERTIFIED TO BE AN ACCURATE
TRANSCRIPTION OF MY STENOGRAPHIC NOTES IN THE
ABOVE-ENTITLED MATTER.

S/Vincent Russoniello
Vincent Russoniello, CCR
Certificate No. 675

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